



Clinical trial results:

A Placebo-Controlled, Double-Blind, Parallel-Group, Bayesian Adaptive Randomization Design and Dose Regimen-Finding Study With an Open-Label Extension Phase to Evaluate Safety, Tolerability, and Efficacy of BAN2401 in Subjects With Early Alzheimer's Disease

Summary

EudraCT number	2012-002843-11
Trial protocol	IT SE DE GB NL ES
Global end of trial date	10 December 2024

Results information

Result version number	v1 (current)
This version publication date	26 December 2025
First version publication date	26 December 2025

Trial information

Trial identification

Sponsor protocol code	BAN2401-G000-201
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01767311
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Eisai Ltd.
Sponsor organisation address	European Knowledge Centre Mosquito Way, Hatfield, Hertfordshire, United Kingdom, AL10 9SN
Public contact	Eisai Europe Ltd., EMEA Medical Information, +44 (0)208 600 1400, EUMedInfo@eisai.net
Scientific contact	Eisai Europe Ltd., EMEA Medical Information, +44 (0)208 600 1400, EUMedInfo@eisai.net

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	10 December 2024
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	10 December 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objectives of the core phase were to evaluate the efficacy of BAN2401 compared to placebo by establishing the dose regimen with at least 90% of the maximum effective dose (dmax) treatment effect (ED90) for BAN2401 on the Alzheimer's Disease Composite Score (ADCOMS) at 12 months of treatment in subjects with Early Alzheimer's Disease (EAD), defined as mild cognitive impairment (MCI) due to Alzheimer's disease (AD) – intermediate likelihood or mild AD dementia and to assess the safety and tolerability of 3 doses and 2 dose regimens of BAN2401 in subjects with EAD. The primary objective of the extension phase was to evaluate the long-term safety and tolerability of lecanemab in subjects with Early Alzheimer's Disease.

Protection of trial subjects:

This study was performed in full compliance with International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and all applicable local Good Clinical Practice (GCP) and regulations. This study is to be conducted in compliance with the protocol and in compliance with the EU Clinical Trial Regulation (CTR). All required study documentation is archived as required by regulatory authorities.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 December 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 43
Country: Number of subjects enrolled	Germany: 7
Country: Number of subjects enrolled	Spain: 32
Country: Number of subjects enrolled	France: 2
Country: Number of subjects enrolled	United Kingdom: 4
Country: Number of subjects enrolled	Italy: 19
Country: Number of subjects enrolled	Japan: 34
Country: Number of subjects enrolled	Korea, Republic of: 19
Country: Number of subjects enrolled	Netherlands: 1
Country: Number of subjects enrolled	Sweden: 8
Country: Number of subjects enrolled	United States: 685
Worldwide total number of subjects	854
EEA total number of subjects	69

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	170
From 65 to 84 years	639
85 years and over	45

Subject disposition

Recruitment

Recruitment details:

This study has been conducted in two phases: Core Study Phase and an Open-Label Extension (OLE) Phase. Subjects took part in the Core study at 149 investigative sites across the North America, Europe and Asia-Pacific. The OLE Phase was conducted at 56 investigative sites across the United States, Europe and Asia-Pacific.

Pre-assignment

Screening details:

A total of 3267 subjects were screened, of which 2411 subjects were screen failures, and 856 subjects were randomized. Out of 856, 854 subjects were treated in Core Study Phase, and 180 subjects were enrolled and treated in OLE Phase.

Period 1

Period 1 title	Core Study Phase (18 months)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Core Study Phase: Placebo

Arm description:

Subjects received lecanemab matching-placebo as 60-minute intravenous (IV) infusions, biweekly or monthly, up to 18 months. Subjects were followed up for 3 months after last dose of lecanemab matched placebo in core study phase.

Arm type	Placebo
Investigational medicinal product name	Lecanemab matching-placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Lecanemab matching-placebo as 60-minute IV infusions, biweekly or monthly, up to 18 months.

Arm title	Core Study Phase: Lecanemab 2.5 mg/kg Biweekly
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Arm description:

Subjects received lecanemab 2.5 milligrams per kilogram (mg/kg) as 60-minute IV infusions, biweekly, up to 18 months. Subjects were followed up for 3 months after last dose of lecanemab in core study phase.

Arm type	Experimental
Investigational medicinal product name	Lecanemab 2.5 mg/kg
Investigational medicinal product code	BAN2401
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Lecanemab 2.5 mg/kg as 60-minute IV infusions, biweekly, up to 18 months.

Arm title	Core Study Phase: Lecanemab 5 mg/kg Monthly
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Arm description:

Subjects received lecanemab 5 mg/kg as 60-minute IV infusions, monthly, up to 18 months. Subjects were followed up for 3 months after last dose of lecanemab in core study phase.

Arm type	Experimental
Investigational medicinal product name	Lecanemab 5mg/kg
Investigational medicinal product code	BAN2401
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Lecanemab 5mg/kg as 60-minute IV infusions, monthly, up to 18 months.

Arm title	Core Study Phase: Lecanemab 5 mg/kg Biweekly
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Arm description:

Subjects received lecanemab 5 mg/kg as 60-minute IV infusions, biweekly, up to 18 months. Subjects were followed up for 3 months after last dose of lecanemab in core study phase.

Arm type	Experimental
Investigational medicinal product name	Lecanemab 5mg/kg
Investigational medicinal product code	BAN2401
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Lecanemab 5mg/kg as 60-minute IV infusions, biweekly, up to 18 months.

Arm title	Core Study Phase: Lecanemab 10 mg/kg Monthly
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Arm description:

Subjects received lecanemab 10 mg/kg as 60-minute IV infusions, monthly, up to 18 months. Subjects were followed up for 3 months after last dose of lecanemab in core study phase.

Arm type	Experimental
Investigational medicinal product name	Lecanemab 10mg/kg
Investigational medicinal product code	BAN2401
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Lecanemab 10mg/kg as 60-minute IV infusions, monthly, up to 18 months.

Arm title	Core Study Phase: Lecanemab 10 mg/kg Biweekly
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Arm description:

Subjects received lecanemab 10 mg/kg as 60-minute IV infusions, biweekly, up to 18 months. Subjects were followed up for 3 months after last dose of lecanemab in core study phase.

Arm type	Experimental
Investigational medicinal product name	Lecanemab 10mg/kg
Investigational medicinal product code	BAN2401
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Lecanemab 10mg/kg as 60-minute IV infusions, biweekly, up to 18 months.

Number of subjects in period 1	Core Study Phase: Placebo	Core Study Phase: Lecanemab 2.5 mg/kg Biweekly	Core Study Phase: Lecanemab 5 mg/kg Monthly
Started	245	52	51
Full Analysis Set (FAS)	238	52	48
Safety Analysis Set (SAS)	245	52	51
PD Analysis Set (Amyloid PET)	99 ^[1]	28 ^[2]	28 ^[3]
Completed	177	35	37
Not completed	68	17	14
Consent withdrawn by subject	23	1	5
Adverse event, non-fatal	10	4	2
Other	13	7	4
Subject Choice	15	5	2
Lost to follow-up	7	-	1

Number of subjects in period 1	Core Study Phase: Lecanemab 5 mg/kg Biweekly	Core Study Phase: Lecanemab 10 mg/kg Monthly	Core Study Phase: Lecanemab 10 mg/kg Biweekly
Started	92	253	161
Full Analysis Set (FAS)	89	246	152
Safety Analysis Set (SAS)	92	253	161
PD Analysis Set (Amyloid PET)	27 ^[4]	89 ^[5]	44 ^[6]
Completed	61	155	87
Not completed	31	98	74
Consent withdrawn by subject	13	37	20
Adverse event, non-fatal	5	23	12
Other	4	20	31
Subject Choice	7	14	8
Lost to follow-up	2	4	3

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Only applicable subjects were present in this analysis set.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Only applicable subjects were present in this analysis set.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Only applicable subjects were present in this analysis set.

[4] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Only applicable subjects were present in this analysis set.

[5] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that

completed, minus those who left.

Justification: Only applicable subjects were present in this analysis set.

[6] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Only applicable subjects were present in this analysis set.

Period 2

Period 2 title	OLE Phase (60 months)
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	OLE Phase: Lecanemab 10 mg/kg Biweekly
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Arm description:

Subjects received lecanemab 10 mg/kg as 60-minute IV infusions, biweekly, up to 60 months. Subjects were followed up for 3 months after last dose of lecanemab in OLE phase.

Arm type	Experimental
Investigational medicinal product name	Lecanemab 10mg/kg
Investigational medicinal product code	BAN2401
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Lecanemab 10mg/kg as 60-minute IV infusions, biweekly, up to 60 months.

Number of subjects in period 2^[7]	OLE Phase: Lecanemab 10 mg/kg Biweekly
Started	180
Treated	180
Coming from Core Part: Placebo	45
Coming from Core-2.5,5mg/kgQ2W,5 mg/kgQ4W	37 ^[8]
Coming from Core Part-10mg/kgQ4W	60
Coming from Core Part-10mg/kgQ2W	38 ^[9]
Safety Analysis Set (SAS)	180
PD Analysis Set (Amyloid PET)	105
Completed	39
Not completed	141
Consent withdrawn by subject	37
Transition To Commercial LEQEMBI	18
Adverse event, non-fatal	12
Subject Choice	37
Other	22
Lost to follow-up	3

Notes:

[7] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: The number of subjects who enrolled for OLE phase were different and not equal to that of the core phase.

[8] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Only applicable subjects from core phase were part of this milestone.

[9] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Only applicable subjects were present in this analysis set.

Baseline characteristics

Reporting groups

Reporting group title	Core Study Phase: Placebo
Reporting group description: Subjects received lecanemab matching-placebo as 60-minute intravenous (IV) infusions, biweekly or monthly, up to 18 months. Subjects were followed up for 3 months after last dose of lecanemab matched placebo in core study phase.	
Reporting group title	Core Study Phase: Lecanemab 2.5 mg/kg Biweekly
Reporting group description: Subjects received lecanemab 2.5 milligrams per kilogram (mg/kg) as 60-minute IV infusions, biweekly, up to 18 months. Subjects were followed up for 3 months after last dose of lecanemab in core study phase.	
Reporting group title	Core Study Phase: Lecanemab 5 mg/kg Monthly
Reporting group description: Subjects received lecanemab 5 mg/kg as 60-minute IV infusions, monthly, up to 18 months. Subjects were followed up for 3 months after last dose of lecanemab in core study phase.	
Reporting group title	Core Study Phase: Lecanemab 5 mg/kg Biweekly
Reporting group description: Subjects received lecanemab 5 mg/kg as 60-minute IV infusions, biweekly, up to 18 months. Subjects were followed up for 3 months after last dose of lecanemab in core study phase.	
Reporting group title	Core Study Phase: Lecanemab 10 mg/kg Monthly
Reporting group description: Subjects received lecanemab 10 mg/kg as 60-minute IV infusions, monthly, up to 18 months. Subjects were followed up for 3 months after last dose of lecanemab in core study phase.	
Reporting group title	Core Study Phase: Lecanemab 10 mg/kg Biweekly
Reporting group description: Subjects received lecanemab 10 mg/kg as 60-minute IV infusions, biweekly, up to 18 months. Subjects were followed up for 3 months after last dose of lecanemab in core study phase.	

Reporting group values	Core Study Phase: Placebo	Core Study Phase: Lecanemab 2.5 mg/kg Biweekly	Core Study Phase: Lecanemab 5 mg/kg Monthly
Number of subjects	245	52	51
Age Categorical Units: subjects			
<=18 years	0	0	0
Between 18 and 65 years	56	11	9
>=65 years	189	41	42
Sex: Female, Male Units: subjects			
Female	138	26	26
Male	107	26	25
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	10	4	1
Not Hispanic or Latino	235	48	50
Unknown or Not Reported	0	0	0
Race/Ethnicity, Customized Units: Subjects			
White	222	48	49
Black or African American	5	2	1

Chinese	1	0	0
Japanese	10	1	0
Other Asian	6	1	1
American Indian or Alaska Native	0	0	0
Native Hawaiian or other Pacific Islander	0	0	0
Other	1	0	0
Missing	0	0	0

Reporting group values	Core Study Phase: Lecanemab 5 mg/kg Biweekly	Core Study Phase: Lecanemab 10 mg/kg Monthly	Core Study Phase: Lecanemab 10 mg/kg Biweekly
Number of subjects	92	253	161
Age Categorical Units: subjects			
<=18 years	0	0	0
Between 18 and 65 years	20	46	28
>=65 years	72	207	133
Sex: Female, Male Units: subjects			
Female	50	112	70
Male	42	141	91
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	3	10	10
Not Hispanic or Latino	89	243	151
Unknown or Not Reported	0	0	0
Race/Ethnicity, Customized Units: Subjects			
White	76	228	150
Black or African American	4	5	4
Chinese	0	0	0
Japanese	6	12	5
Other Asian	3	5	2
American Indian or Alaska Native	0	0	0
Native Hawaiian or other Pacific Islander	0	0	0
Other	3	3	0
Missing	0	0	0

Reporting group values	Total		
Number of subjects	854		
Age Categorical Units: subjects			
<=18 years	0		
Between 18 and 65 years	170		
>=65 years	684		
Sex: Female, Male Units: subjects			
Female	422		
Male	432		

Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	38		
Not Hispanic or Latino	816		
Unknown or Not Reported	0		
Race/Ethnicity, Customized			
Units: Subjects			
White	773		
Black or African American	21		
Chinese	1		
Japanese	34		
Other Asian	18		
American Indian or Alaska Native	0		
Native Hawaiian or other Pacific Islander	0		
Other	7		
Missing	0		

End points

End points reporting groups

Reporting group title	Core Study Phase: Placebo
Reporting group description: Subjects received lecanemab matching-placebo as 60-minute intravenous (IV) infusions, biweekly or monthly, up to 18 months. Subjects were followed up for 3 months after last dose of lecanemab matched placebo in core study phase.	
Reporting group title	Core Study Phase: Lecanemab 2.5 mg/kg Biweekly
Reporting group description: Subjects received lecanemab 2.5 milligrams per kilogram (mg/kg) as 60-minute IV infusions, biweekly, up to 18 months. Subjects were followed up for 3 months after last dose of lecanemab in core study phase.	
Reporting group title	Core Study Phase: Lecanemab 5 mg/kg Monthly
Reporting group description: Subjects received lecanemab 5 mg/kg as 60-minute IV infusions, monthly, up to 18 months. Subjects were followed up for 3 months after last dose of lecanemab in core study phase.	
Reporting group title	Core Study Phase: Lecanemab 5 mg/kg Biweekly
Reporting group description: Subjects received lecanemab 5 mg/kg as 60-minute IV infusions, biweekly, up to 18 months. Subjects were followed up for 3 months after last dose of lecanemab in core study phase.	
Reporting group title	Core Study Phase: Lecanemab 10 mg/kg Monthly
Reporting group description: Subjects received lecanemab 10 mg/kg as 60-minute IV infusions, monthly, up to 18 months. Subjects were followed up for 3 months after last dose of lecanemab in core study phase.	
Reporting group title	Core Study Phase: Lecanemab 10 mg/kg Biweekly
Reporting group description: Subjects received lecanemab 10 mg/kg as 60-minute IV infusions, biweekly, up to 18 months. Subjects were followed up for 3 months after last dose of lecanemab in core study phase.	
Reporting group title	OLE Phase: Lecanemab 10 mg/kg Biweekly
Reporting group description: Subjects received lecanemab 10 mg/kg as 60-minute IV infusions, biweekly, up to 60 months. Subjects were followed up for 3 months after last dose of lecanemab in OLE phase.	
Subject analysis set title	OLE Phase: Lecanemab 10 mg/kg Biweekly
Subject analysis set type	Safety analysis
Subject analysis set description: Subjects received lecanemab 10 mg/kg as 60-minute IV infusions, biweekly, up to 60 months. Subjects were followed up for 3 months after last dose of lecanemab in OLE phase.	
Subject analysis set title	Core Phase: Lecanemab 10 mg/kg Biweekly
Subject analysis set type	Safety analysis
Subject analysis set description: Subjects received lecanemab 10 mg/kg as 60-minute IV infusions, biweekly, up to 18 months. Subjects were followed up for 3 months after last dose of lecanemab in core study phase.	
Subject analysis set title	OLE Phase: Newly Treated Core Placebo
Subject analysis set type	Full analysis
Subject analysis set description: Subjects randomized to placebo in the Core Study and newly-treated with lecanemab 10 mg/kg, biweekly, in the OLE phase.	
Subject analysis set title	OLE Phase: Re-treated Core Lower Doses
Subject analysis set type	Full analysis
Subject analysis set description: Subjects randomized to 2.5 mg/kg biweekly, 5 mg/kg monthly, or 5 mg/kg biweekly in the Core Study and re-treated with lecanemab 10 mg/kg, biweekly, in the OLE phase.	
Subject analysis set title	OLE Phase: Re-treated Core 10 mg/kg Monthly
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects randomized to 10 mg/kg monthly in the Core Study and re-treated with lecanemab 10 mg/kg, biweekly, in the OLE phase.

Subject analysis set title	OLE Phase: Re-treated Core 10 mg/kg Biweekly
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects randomized to 10 mg/kg biweekly in the Core Study and re-treated with lecanemab 10 mg/kg, biweekly, in the OLE phase.

Subject analysis set title	OLE Phase: Newly Treated Core Placebo
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects randomized to placebo in the Core Study and newly-treated with lecanemab 10 mg/kg, biweekly, in the OLE phase.

Subject analysis set title	OLE Phase: Re-treated Core Lower Doses
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects randomized to 2.5 mg/kg biweekly, 5 mg/kg monthly, or 5 mg/kg biweekly in the Core Study and re-treated with lecanemab 10 mg/kg, biweekly, in the OLE phase.

Subject analysis set title	OLE Phase: Re-treated Core 10 mg/kg Monthly
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects randomized to 10 mg/kg monthly in the Core Study and re-treated with lecanemab 10 mg/kg, biweekly, in the OLE phase.

Subject analysis set title	OLE Phase: Re-treated Core 10 mg/kg Biweekly
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects randomized to 10 mg/kg biweekly in the Core Study and re-treated with lecanemab 10 mg/kg, biweekly, in the OLE phase.

Primary: Core Study Phase: Change from Baseline in Alzheimer's Disease Composite Score (ADCOMS) at Month 12

End point title	Core Study Phase: Change from Baseline in Alzheimer's Disease Composite Score (ADCOMS) at Month 12 ^[1]
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End point description:

The ADCOMS is a composite score that comprises 4/14 items from the Alzheimer's Disease Assessment Scale-cognitive subscale (ADAS-cog), 2 items from the Mini Mental State Examination (MMSE), and all items from the Clinical Dementia Rating (CDR). Composite score is derived from the variables from the 12 items, and ranges from 0 to 1.97, where higher score means greater impairment. Change from baseline was analyzed using Bayesian analysis. Data presented are posterior mean and posterior standard deviation. The primary analysis indicated that the 10mg/kg biweekly dose had a 64% probability of being better than placebo with 25% less decline. FAS was the group of randomized subjects who received at least 1 dose of study drug and had baseline and at least 1 post dose primary efficacy measurement.

End point type	Primary
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End point timeframe:

Core Study Phase: at Month 12

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was evaluated for this end point.

End point values	Core Study Phase: Placebo	Core Study Phase: Lecanemab 2.5 mg/kg Biweekly	Core Study Phase: Lecanemab 5 mg/kg Monthly	Core Study Phase: Lecanemab 5 mg/kg Biweekly
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	238	52	48	89
Units: score on a scale				
arithmetic mean (standard deviation)	0.113 (\pm 0.012)	0.134 (\pm 0.024)	0.119 (\pm 0.021)	0.116 (\pm 0.016)

End point values	Core Study Phase: Lecanemab 10 mg/kg Monthly	Core Study Phase: Lecanemab 10 mg/kg Biweekly		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	246	152		
Units: score on a scale				
arithmetic mean (standard deviation)	0.084 (\pm 0.011)	0.077 (\pm 0.014)		

Statistical analyses

No statistical analyses for this end point

Primary: Core Study Phase: Number of Subjects with all Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs)

End point title	Core Study Phase: Number of Subjects with all Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs) ^[2]
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End point description:

A TEAE is defined as an adverse event (AE) that emerged during treatment or within 90 days following last dose of study drug, having been absent at pretreatment (Baseline) or reemerged during treatment, having been present at pretreatment but stopped before treatment, or worsened in severity during treatment relative to pretreatment state, when AE was continuous. A SAE is any untoward medical occurrence that at any dose: results in death; is life-threatening (that is, subject is at immediate risk of death from AE as it occurs, this does not include an event that, has it occurred in a more severe form or is allowed to continue, might have caused death); requires inpatient hospitalization or prolongation of existing hospitalization; results in persistent or significant disability or incapacity; is a congenital anomaly or birth defect (in child of a subject who is exposed to study drug). Safety Analysis Set.

End point type	Primary
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End point timeframe:

From first dose of the study drug (Week 1) up to 90 days after last dose of study drug (up to 21 months)

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was evaluated for this end point.

End point values	Core Study Phase: Placebo	Core Study Phase: Lecanemab 2.5 mg/kg Biweekly	Core Study Phase: Lecanemab 5 mg/kg Monthly	Core Study Phase: Lecanemab 5 mg/kg Biweekly
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	245	52	51	92
Units: subjects				
TEAEs	216	46	48	81
SAEs	43	10	4	16

End point values	Core Study Phase: Lecanemab 10 mg/kg Monthly	Core Study Phase: Lecanemab 10 mg/kg Biweekly		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	253	161		
Units: subjects				
TEAEs	238	139		
SAEs	31	25		

Statistical analyses

No statistical analyses for this end point

Primary: OLE Phase: Number of Subjects with all TEAEs and SAEs

End point title	OLE Phase: Number of Subjects with all TEAEs and SAEs ^[3]
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End point description:

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 pretreatment state, when AE was continuous. A SAE is any untoward medical occurrence that at any dose: results in death; is life-threatening (that is, subject is at immediate risk of death from the adverse event as it occurs, this does not include an event that, has it occurred in a more severe form or is allowed to continue, might have caused death); requires inpatient hospitalization or prolongation of existing hospitalization; results in persistent or significant disability or incapacity; is a congenital anomaly or birth defect (in the child of a subject who is exposed to the study drug). SAS was group of subjects who received at least one active dose of study drug.

End point type	Primary
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End point timeframe:

From first dose of the study drug (Week 1) up to 30 days after last dose of study drug (up to 61 months)

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This end point was assessed for OLE phase only.

End point values	OLE Phase: Lecanemab 10 mg/kg Biweekly			
Subject group type	Reporting group			
Number of subjects analysed	180			
Units: subjects				
TEAEs	173			
SAEs	60			

Statistical analyses

No statistical analyses for this end point

Secondary: Core Study Phase: Change from Baseline at Months 12 and 18 in Brain Amyloid Pathophysiology as Measured by Amyloid Positron Emission Tomography (PET)

End point title	Core Study Phase: Change from Baseline at Months 12 and 18 in Brain Amyloid Pathophysiology as Measured by Amyloid Positron Emission Tomography (PET)
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End point description:

Amyloid plaque load was identified by PET using 2 tracers (florbetapir and flutemetamol). The imaging uptake was determined via standard uptake value ratio (SUVr) versus a reference region. The SUVr is a quantitative tool and refers to the ratio of the global cortical average as compared to a reference region of choice. Whole cerebellum mask was used as the reference region of choice in this study. PET SUVr values were converted to Centiloid units. Centiloid scale anchor points are 0 and 100, where 0 represents a high-certainty amyloid negative scan and 100 represents the amount of global amyloid deposition. The pharmacodynamic (PD) analysis set was the group of subjects who had sufficient amyloid PET data to derive at least 1 amyloid PET parameter. Here, 'n' refers to number of subjects analyzed at given time points.

End point type	Secondary
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End point timeframe:

Core Study Phase: at Months 12 and 18

End point values	Core Study Phase: Placebo	Core Study Phase: Lecanemab 2.5 mg/kg Biweekly	Core Study Phase: Lecanemab 5 mg/kg Monthly	Core Study Phase: Lecanemab 5 mg/kg Biweekly
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	99	28	28	27
Units: centiloids				
least squares mean (standard error)				
Change at Month 12 (n= 96, 27, 27, 25, 88, 43)	-2.154 (± 2.448)	-14.733 (± 4.345)	-16.877 (± 4.350)	-37.796 (± 4.522)
Change at Month 18 (n= 88, 23, 23, 24, 82, 37)	1.004 (± 2.651)	-22.404 (± 4.822)	-31.168 (± 4.844)	-46.217 (± 4.879)

End point values	Core Study Phase:	Core Study Phase:		
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	Lecanemab 10 mg/kg Monthly	Lecanemab 10 mg/kg Biweekly		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	89	44		
Units: centiloids				
least squares mean (standard error)				
Change at Month 12 (n= 96, 27, 27, 25, 88, 43)	-41.704 (\pm 2.682)	-62.827 (\pm 3.486)		
Change at Month 18 (n= 88, 23, 23, 24, 82, 37)	-53.412 (\pm 2.877)	-72.495 (\pm 3.870)		

Statistical analyses

No statistical analyses for this end point

Secondary: Core Study Phase: Change from Baseline in ADCOMS at Month 18

End point title	Core Study Phase: Change from Baseline in ADCOMS at Month 18
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End point description:

The ADCOMS is a composite score that comprises 4/14 items from the ADAS-cog, 2 items from the MMSE, and all items from the CDR. Composite score is derived from the variables from the 12 items, and ranges from 0 to 1.97, where higher score means greater impairment. FAS was the group of randomized subjects who received at least 1 dose of study drug and had baseline and at least 1 post dose primary efficacy measurement. Here, 'Number of Subjects Analyzed' refers to number of subjects analyzed at given time point.

End point type	Secondary
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End point timeframe:

Core Study Phase: at Month 18

End point values	Core Study Phase: Placebo	Core Study Phase: Lecanemab 2.5 mg/kg Biweekly	Core Study Phase: Lecanemab 5 mg/kg Monthly	Core Study Phase: Lecanemab 5 mg/kg Biweekly
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	160	33	35	61
Units: score on a scale				
least squares mean (standard error)	0.193 (\pm 0.017)	0.173 (\pm 0.035)	0.192 (\pm 0.035)	0.199 (\pm 0.026)

End point values	Core Study Phase: Lecanemab 10 mg/kg Monthly	Core Study Phase: Lecanemab 10 mg/kg Biweekly		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	146	79		
Units: score on a scale				

least squares mean (standard error)	0.166 (\pm 0.018)	0.136 (\pm 0.022)		
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Statistical analyses

No statistical analyses for this end point

Secondary: Core Study Phase: Change from Baseline in Clinical Dementia Rating-Sum of Boxes (CDR-SB) at Months 12 and 18

End point title	Core Study Phase: Change from Baseline in Clinical Dementia Rating- Sum of Boxes (CDR-SB) at Months 12 and 18
End point description:	
<p>The CDR is a clinical scale that describes 5 degrees of impairment in performance on each of 6 categories of function including memory, orientation, judgment and problem solving, community affairs, home and hobbies, and personal care. The ratings of degree of impairment obtained on each of the 6 categories of function are synthesized into 1 global rating of dementia CDR score (ranging from 0 to 3). A sum of boxes score provides an additional measure of change where each category has a maximum possible score of 3 points and the total score is a sum of the category scores giving a total possible score of 0 to 18 with higher scores indicating more impairment. The full analysis set was the group of randomized subjects who received at least 1 dose of study drug and had baseline and at least 1 post dose primary efficacy measurement. Here, 'n' refers to number of subjects analyzed at given time points.</p>	
End point type	Secondary
End point timeframe:	
Core Study Phase: at Months 12 and 18	

End point values	Core Study Phase: Placebo	Core Study Phase: Lecanemab 2.5 mg/kg Biweekly	Core Study Phase: Lecanemab 5 mg/kg Monthly	Core Study Phase: Lecanemab 5 mg/kg Biweekly
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	238	52	48	89
Units: score on a scale				
least squares mean (standard error)				
Change at Month 12 (n= 188, 38, 42, 70, 166, 94)	0.911 (\pm 0.124)	1.038 (\pm 0.257)	1.277 (\pm 0.253)	0.945 (\pm 0.194)
Change at Month 18 (n= 161, 34, 36, 67, 149, 84)	1.499 (\pm 0.160)	1.227 (\pm 0.338)	1.713 (\pm 0.334)	1.463 (\pm 0.250)

End point values	Core Study Phase: Lecanemab 10 mg/kg Monthly	Core Study Phase: Lecanemab 10 mg/kg Biweekly		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	246	152		
Units: score on a scale				
least squares mean (standard error)				

Change at Month 12 (n= 188, 38, 42, 70, 166, 94)	0.705 (± 0.133)	0.568 (± 0.163)		
Change at Month 18 (n= 161, 34, 36, 67, 149, 84)	1.248 (± 0.169)	1.102 (± 0.213)		

Statistical analyses

No statistical analyses for this end point

Secondary: Core Study Phase: Change from Baseline in Alzheimer Disease Assessment Scale - Cognitive Subscale (ADAS-Cog) at Months 12 and 18

End point title	Core Study Phase: Change from Baseline in Alzheimer Disease Assessment Scale - Cognitive Subscale (ADAS-Cog) at Months 12 and 18
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End point description:

The ADAS-Cog is a cognitive scale which evaluates 14 items- memory (word recall, delayed word recall, and word recognition), reasoning (following commands), language (naming, comprehension), orientation, ideational praxis (placing letter in envelope), constructional praxis (copying geometric designs), spoken language, language comprehension, word finding difficulty, ability to remember test instructions, maze, and number cancellation. The total score ranges from 0 to 90. Higher score indicates greater cognitive impairment. The full analysis set was the group of randomized subjects who received at least 1 dose of study drug and had baseline and at least 1 post dose primary efficacy measurement. Here, 'n' refers to number of subjects analyzed at given time points.

End point type	Secondary
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End point timeframe:

Core Study Phase: at Months 12 and 18

End point values	Core Study Phase: Placebo	Core Study Phase: Lecanemab 2.5 mg/kg Biweekly	Core Study Phase: Lecanemab 5 mg/kg Monthly	Core Study Phase: Lecanemab 5 mg/kg Biweekly
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	238	52	48	89
Units: score on a scale				
least squares mean (standard error)				
Change at Month 12 (n= 186, 38, 41, 69, 164, 94)	2.842 (± 0.501)	4.251 (± 1.005)	3.426 (± 1.005)	3.297 (± 0.766)
Change at Month 18 (n= 158, 33, 34, 61, 146, 79)	4.902 (± 0.617)	5.574 (± 1.275)	5.746 (± 1.279)	4.506 (± 0.959)

End point values	Core Study Phase: Lecanemab 10 mg/kg Monthly	Core Study Phase: Lecanemab 10 mg/kg Biweekly		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	246	152		
Units: score on a scale				
least squares mean (standard error)				

Change at Month 12 (n= 186, 38, 41, 69, 164, 94)	2.200 (± 0.536)	1.481 (± 0.648)		
Change at Month 18 (n= 158, 33, 34, 61, 146, 79)	4.624 (± 0.652)	2.588 (± 0.811)		

Statistical analyses

No statistical analyses for this end point

Secondary: Core Study Phase: Change from Baseline in Cerebrospinal fluid (CSF) Biomarker Levels at Months 12 and 18

End point title	Core Study Phase: Change from Baseline in Cerebrospinal fluid (CSF) Biomarker Levels at Months 12 and 18
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End point description:

The measurement of the amyloid proteins- Aβ(1-42) (amyloid beta monomer from amino acid 1 to 42), total (t)-tau, and phospho (p)-tau in CSF have been shown to be important biomarkers for alzheimer's disease. The PD analysis set was the group of subjects who had sufficient CSF data to derive at least 1 CSF parameter. Here, 'n' refers to number of subjects analyzed at given time points.

End point type	Secondary
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End point timeframe:

Core Study Phase: at Months 12 and 18

End point values	Core Study Phase: Placebo	Core Study Phase: Lecanemab 2.5 mg/kg Biweekly	Core Study Phase: Lecanemab 5 mg/kg Monthly	Core Study Phase: Lecanemab 5 mg/kg Biweekly
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	7	13	20
Units: picogram per milliliter (pg/mL)				
least squares mean (standard error)				
Month 12 in Aβ(1-42) (n= 22, 7, 13, 19, 16, 10)	-8.008 (± 36.952)	49.921 (± 57.175)	89.009 (± 44.816)	152.271 (± 39.993)
Month 18 in Aβ(1-42) (n= 19, 5, 10, 14, 13, 9)	-3.639 (± 38.228)	130.940 (± 63.467)	104.253 (± 48.358)	168.906 (± 43.762)
Month 12 in t-tau (n= 17, 6, 8, 14, 10, 7)	-25.680 (± 47.937)	-92.678 (± 72.662)	-51.163 (± 65.398)	-61.933 (± 57.301)
Month 18 in t-tau (n= 15, 4, 6, 12, 8, 7)	-70.490 (± 46.075)	-154.465 (± 76.475)	-128.914 (± 67.208)	-92.441 (± 56.026)
Month 12 in p -tau (n= 22, 7, 13, 19, 16, 10)	3.258 (± 4.834)	-2.451 (± 7.785)	-2.135 (± 5.848)	-3.810 (± 5.211)
Month 18 in p -tau (n= 19, 5, 10, 14, 13, 10)	1.436 (± 4.335)	-6.496 (± 7.323)	-2.201 (± 5.434)	-10.508 (± 5.073)

End point values	Core Study Phase: Lecanemab 10 mg/kg Monthly	Core Study Phase: Lecanemab 10 mg/kg Biweekly		
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Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	12		
Units: picogram per milliliter (pg/mL)				
least squares mean (standard error)				
Month 12 in Aβ(1-42) (n= 22, 7, 13, 19, 16, 10)	137.036 (± 42.042)	286.542 (± 51.385)		
Month 18 in Aβ(1-42) (n= 19, 5, 10, 14, 13, 9)	193.388 (± 44.454)	392.445 (± 53.603)		
Month 12 in t-tau (n= 17, 6, 8, 14, 10, 7)	-153.214 (± 58.215)	-39.101 (± 66.565)		
Month 18 in t-tau (n= 15, 4, 6, 12, 8, 7)	-102.221 (± 57.606)	66.279 (± 59.639)		
Month 12 in p -tau (n= 22, 7, 13, 19, 16, 10)	-15.732 (± 5.542)	-9.732 (± 6.606)		
Month 18 in p -tau (n= 19, 5, 10, 14, 13, 10)	-11.874 (± 5.023)	-10.880 (± 5.492)		

Statistical analyses

No statistical analyses for this end point

Secondary: Core Study Phase: Change from Baseline in Total Hippocampal Volume at Months 6, 12 and 18

End point title	Core Study Phase: Change from Baseline in Total Hippocampal Volume at Months 6, 12 and 18
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End point description:

Total hippocampal volume is measured by volumetric magnetic resonance imaging (vMRI). Volumetric imaging is a 3D technique where all the MRI signals are collected from the entire tissue sample and imaged as a whole entity, therefore providing a high signal to noise ratio. Total hippocampal volume is calculated by summing up right and left hippocampal volumes. The PD analysis set was the group of subjects who had sufficient vMRI data to derive at least 1 vMRI parameter. Here, 'n' refers to number of subjects analyzed at given time points.

End point type	Secondary
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End point timeframe:

Core Study Phase: at Months 6, 12 and 18

End point values	Core Study Phase: Placebo	Core Study Phase: Lecanemab 2.5 mg/kg Biweekly	Core Study Phase: Lecanemab 5 mg/kg Monthly	Core Study Phase: Lecanemab 5 mg/kg Biweekly
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	209	41	46	73
Units: cubic millimeters				
least squares mean (standard error)				
Change at Month 6 (n= 199, 39, 44, 72, 185, 91)	-112.881 (± 9.973)	-100.640 (± 19.511)	-127.152 (± 18.495)	-112.335 (± 15.102)
Change at Month 12 (n= 178, 40, 43, 66, 158, 83)	-187.122 (± 10.196)	-189.687 (± 19.422)	-200.721 (± 18.640)	-213.074 (± 15.376)
Change at Month 18 (n= 162, 34, 39, 55, 144, 72)	-257.297 (± 10.394)	-305.254 (± 20.161)	-304.600 (± 19.053)	-297.469 (± 15.955)

End point values	Core Study Phase: Lecanemab 10 mg/kg Monthly	Core Study Phase: Lecanemab 10 mg/kg Biweekly		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	188	99		
Units: cubic millimeters				
least squares mean (standard error)				
Change at Month 6 (n= 199, 39, 44, 72, 185, 91)	-99.922 (\pm 10.981)	-120.262 (\pm 13.979)		
Change at Month 12 (n= 178, 40, 43, 66, 158, 83)	-172.774 (\pm 11.271)	-204.058 (\pm 14.233)		
Change at Month 18 (n= 162, 34, 39, 55, 144, 72)	-264.868 (\pm 11.448)	-276.740 (\pm 14.681)		

Statistical analyses

No statistical analyses for this end point

Secondary: Core Study Phase: Change from Baseline in Left and Right Hippocampal Volume at Months 6, 12 and 18

End point title	Core Study Phase: Change from Baseline in Left and Right Hippocampal Volume at Months 6, 12 and 18
End point description:	
Left Hippocampal Volume (LHV) and Right Hippocampus Volume (RHV) are measured by vMRI. Volumetric imaging is a 3D technique where all the MRI signals are collected from the entire tissue sample and imaged as a whole entity, therefore providing a high signal to noise ratio. Left and right hippocampal volumes represent a summary measure in the left and right hippocampal regions. The PD analysis set was the group of subjects who had sufficient vMRI data to derive at least 1 vMRI parameter. Here, 'n' refers to number of subjects analyzed at given time points.	
End point type	Secondary
End point timeframe:	
Core Study Phase: at Months 6, 12 and 18	

End point values	Core Study Phase: Placebo	Core Study Phase: Lecanemab 2.5 mg/kg Biweekly	Core Study Phase: Lecanemab 5 mg/kg Monthly	Core Study Phase: Lecanemab 5 mg/kg Biweekly
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	209	41	46	73
Units: cubic millimeters				
least squares mean (standard error)				
Month 6 in LHV (n= 199, 39, 44, 72, 185, 91)	-54.087 (\pm 5.457)	-50.434 (\pm 10.664)	-61.886 (\pm 10.120)	-55.660 (\pm 8.263)
Month 12 in LHV (n= 178, 40, 43, 66, 158, 83)	-93.718 (\pm 5.580)	-93.988 (\pm 10.614)	-101.775 (\pm 10.200)	-103.744 (\pm 8.414)

Month 18 in LHV (n= 162, 34, 39, 55, 144, 72)	-129.578 (± 5.689)	-147.500 (± 11.022)	-149.009 (± 10.428)	-149.244 (± 8.734)
Month 6 in RHV (n= 199, 39, 44, 72, 185, 91)	-58.876 (± 5.765)	-51.454 (± 11.299)	-65.724 (± 10.700)	-56.881 (± 8.734)
Month 12 in RHV (n= 178, 40, 43, 66, 158, 53)	-93.503 (± 5.897)	-96.952 (± 11.246)	-99.397 (± 10.785)	-109.513 (± 8.896)
Month 18 in RHV (n= 162, 34, 39, 55, 144, 72)	-127.823 (± 6.014)	-158.981 (± 11.684)	-156.004 (± 11.030)	-148.467 (± 9.239)

End point values	Core Study Phase: Lecanemab 10 mg/kg Monthly	Core Study Phase: Lecanemab 10 mg/kg Biweekly		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	188	99		
Units: cubic millimeters				
least squares mean (standard error)				
Month 6 in LHV (n= 199, 39, 44, 72, 185, 91)	-51.235 (± 6.009)	-65.037 (± 7.650)		
Month 12 in LHV (n= 178, 40, 43, 66, 158, 83)	-89.696 (± 6.169)	-109.026 (± 7.790)		
Month 18 in LHV (n= 162, 34, 39, 55, 144, 72)	-134.749 (± 6.266)	-142.666 (± 8.036)		
Month 6 in RHV (n= 199, 39, 44, 72, 185, 91)	-48.976 (± 6.344)	-55.242 (± 8.085)		
Month 12 in RHV (n= 178, 40, 43, 66, 158, 53)	-83.346 (± 6.515)	-94.972 (± 8.235)		
Month 18 in RHV (n= 162, 34, 39, 55, 144, 72)	-130.389 (± 6.620)	-134.090 (± 8.500)		

Statistical analyses

No statistical analyses for this end point

Secondary: Core Study Phase: Change from Baseline in Whole Brain Volume at Months 6, 12 and 18

End point title	Core Study Phase: Change from Baseline in Whole Brain Volume at Months 6, 12 and 18
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End point description:

Whole brain volume is measured by vMRI. Volumetric imaging is a 3D technique where all the MRI signals are collected from the entire tissue sample and imaged as a whole entity, therefore providing a high signal to noise ratio. Whole brain volume represents a summary measure of total brain parenchyma which includes the cerebrum, basal ganglia, diencephalon, and cerebellum. The PD analysis set was the group of subjects who had sufficient vMRI data to derive at least 1 vMRI parameter. Here, 'n' refers to number of subjects analyzed at given time points.

End point type	Secondary
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End point timeframe:

Core Study Phase: at Months 6, 12 and 18

End point values	Core Study Phase: Placebo	Core Study Phase: Lecanemab 2.5 mg/kg Biweekly	Core Study Phase: Lecanemab 5 mg/kg Monthly	Core Study Phase: Lecanemab 5 mg/kg Biweekly
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	209	41	46	73
Units: cubic millimeters				
least squares mean (standard error)				
Change at Month 6 (n= 198, 38, 43, 72, 183, 91)	-8874.418 (± 885.172)	-10020.371 (± 1732.015)	-13726.830 (± 1656.368)	-11237.195 (± 1339.685)
Change at Month 12 (n= 177, 38, 42, 66, 156, 82)	-15489.162 (± 904.604)	-18027.826 (± 1734.486)	-19721.462 (± 1669.211)	-19616.201 (± 1363.106)
Change at Month 18 (n= 162, 32, 38, 55, 144, 72)	-21775.855 (± 921.131)	-26987.109 (± 1805.216)	-27972.208 (± 1706.449)	-26520.544 (± 1413.525)

End point values	Core Study Phase: Lecanemab 10 mg/kg Monthly	Core Study Phase: Lecanemab 10 mg/kg Biweekly		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	188	99		
Units: cubic millimeters				
least squares mean (standard error)				
Change at Month 6 (n= 198, 38, 43, 72, 183, 91)	-9656.914 (± 979.072)	-12613.175 (± 1240.020)		
Change at Month 12 (n= 177, 38, 42, 66, 156, 82)	-16900.972 (± 1004.379)	-21913.188 (± 1264.436)		
Change at Month 18 (n= 162, 32, 38, 55, 144, 72)	-25030.190 (± 1017.492)	-29894.193 (± 1300.815)		

Statistical analyses

No statistical analyses for this end point

Secondary: Core Study Phase: Change from Baseline in Total Ventricular Volume at Months 6, 12 and 18

End point title	Core Study Phase: Change from Baseline in Total Ventricular Volume at Months 6, 12 and 18
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End point description:

Total ventricular volume is measured by vMRI. Volumetric imaging is a 3D technique where all the MRI signals are collected from the entire tissue sample and imaged as a whole entity, therefore providing a high signal to noise ratio. Total ventricular volume represents a summary measure of total including right and left lateral ventricles, third ventricle and fourth ventricle of brain. The PD analysis set was the group of subjects who had sufficient vMRI data to derive at least 1 vMRI parameter. Here, 'n' refers to number of subjects analyzed at given time points.

End point type	Secondary
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End point timeframe:

Core Study Phase: at Months 6, 12 and 18

End point values	Core Study Phase: Placebo	Core Study Phase: Lecanemab 2.5 mg/kg Biweekly	Core Study Phase: Lecanemab 5 mg/kg Monthly	Core Study Phase: Lecanemab 5 mg/kg Biweekly
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	209	41	46	73
Units: cubic millimeters				
least squares mean (standard error)				
Change at Month 6 (n= 199, 39, 44, 72, 185, 92)	1903.815 (\pm 233.516)	2052.336 (\pm 454.966)	2528.554 (\pm 432.705)	2486.366 (\pm 353.749)
Change at Month 12 (n= 178, 40, 43, 66, 158, 82)	3590.079 (\pm 238.650)	4043.315 (\pm 452.855)	4824.827 (\pm 436.020)	4330.876 (\pm 359.983)
Change at Month 18 (n= 161, 34, 39, 55, 144, 72)	5344.503 (\pm 243.477)	6250.430 (\pm 469.844)	7265.785 (\pm 445.381)	6338.779 (\pm 373.274)

End point values	Core Study Phase: Lecanemab 10 mg/kg Monthly	Core Study Phase: Lecanemab 10 mg/kg Biweekly		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	188	99		
Units: cubic millimeters				
least squares mean (standard error)				
Change at Month 6 (n= 199, 39, 44, 72, 185, 92)	2121.032 (\pm 257.082)	3110.184 (\pm 326.434)		
Change at Month 12 (n= 178, 40, 43, 66, 158, 82)	4322.248 (\pm 263.766)	5529.833 (\pm 333.677)		
Change at Month 18 (n= 161, 34, 39, 55, 144, 72)	6504.053 (\pm 267.760)	7662.459 (\pm 343.216)		

Statistical analyses

No statistical analyses for this end point

Secondary: OLE Phase: Change from OLE Baseline in Brain Amyloid Levels as Measured by Amyloid PET

End point title	OLE Phase: Change from OLE Baseline in Brain Amyloid Levels as Measured by Amyloid PET
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End point description:

Amyloid plaque load was identified by PET using 2 tracers (florbetapir and flutemetamol). The imaging uptake was determined via SUVR versus a reference region. SUVR is a quantitative tool and refers to ratio of global cortical average as compared to a reference region of choice. Whole cerebellum mask was used as reference region of choice in this study. PET SUVR values were converted to Centiloid units. Centiloid scale anchor points are 0 and 100, where 0 represents a high-certainty amyloid negative scan and 100 represents amount of global amyloid deposition. Change from OLE baseline was analyzed using the Mixed Model for Repeated Measures (MMRM) with Core Study treatment group, visit, Core Study treatment group by visit interaction, APOE4 status as fixed effects, and OLE baseline value and Gap duration as covariates. OLE PD Analysis Set was group of subjects who had sufficient PD data to derive

at least 1 PD parameter during OLE Phase.

End point type	Secondary
End point timeframe:	
OLE Phase: at Months 3, 6, 12, 24, 36 and 48	

End point values	OLE Phase: Newly Treated Core Placebo	OLE Phase: Re-treated Core Lower Doses	OLE Phase: Re-treated Core 10 mg/kg Monthly	OLE Phase: Re-treated Core 10 mg/kg Biweekly
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	27 ^[4]	20	36	22
Units: centiloids				
arithmetic mean (standard error)				
Change at Month 3 (n= 9, 9, 18, 10)	-18.260 (± 5.481)	-9.562 (± 5.555)	-10.136 (± 8.045)	-27.575 (± 4.302)
Change at Month 6 (n= 11, 7, 11, 10)	-32.208 (± 5.452)	-11.929 (± 6.833)	-21.253 (± 5.717)	-21.606 (± 4.481)
Change at Month 12 (n= 19, 13, 25, 18)	-50.951 (± 5.070)	-27.162 (± 5.403)	-27.927 (± 6.024)	-22.769 (± 3.868)
Change at Month 24 (n= 17, 14, 26, 13)	-60.300 (± 5.772)	-36.304 (± 5.605)	-34.646 (± 4.417)	-30.715 (± 5.066)
Change at Month 36 (n= 13, 10, 17, 9)	-65.243 (± 7.544)	-38.383 (± 6.356)	-40.367 (± 4.906)	-33.116 (± 5.783)
Change at Month 48 (n= 9, 7, 12, 8)	-66.598 (± 7.185)	-38.249 (± 8.190)	-43.541 (± 5.848)	-32.976 (± 5.655)

Notes:

[4] - Here, 'n' refers to number of subjects analyzed at given timepoints.

Statistical analyses

No statistical analyses for this end point

Secondary: OLE Phase: Change from end of Core Study at the Baseline of OLE Phase in Brain Amyloid Levels as Measured by Amyloid PET

End point title	OLE Phase: Change from end of Core Study at the Baseline of OLE Phase in Brain Amyloid Levels as Measured by Amyloid PET
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End point description:

Amyloid plaque load was identified by PET using 2 tracers (florbetapir and flutemetamol). The imaging uptake was determined via standard uptake value ratio (SUVR) versus a reference region. The SUVR is a quantitative tool and refers to the ratio of the global cortical average as compared to a reference region of choice. Whole cerebellum mask was used as the reference region of choice in this study. PET SUVR values were converted to Centiloid units. Centiloid scale anchor points are 0 and 100, where 0 represents a high-certainty amyloid negative scan and 100 represents the amount of global amyloid deposition. The OLE enrolled set was the group of subjects who were enrolled in OLE phase. Here, 'n' refers to number of subjects analyzed at given time points.

End point type	Secondary
End point timeframe:	
Core Study: at Month 18, OLE Phase: Baseline	

End point values	OLE Phase: Newly Treated Core Placebo	OLE Phase: Re-treated Core Lower Doses	OLE Phase: Re-treated Core 10 mg/kg Monthly	OLE Phase: Re-treated Core 10 mg/kg Biweekly
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	37	60	38
Units: centiloids				
arithmetic mean (standard deviation)				
At end of core study-at Month 18(n= 13,6,24,13)	12.077 (± 27.7765)	-50.610 (± 20.3136)	-54.491 (± 33.4376)	-78.022 (± 27.4337)
Change at OLE Baseline(n= 16,9,26,15)	0.303 (± 25.4131)	-19.673 (± 31.7079)	-43.984 (± 37.7811)	-61.031 (± 37.6563)

Statistical analyses

No statistical analyses for this end point

Secondary: OLE Phase: Percentage of Amyloid Positive Subjects over Time

End point title	OLE Phase: Percentage of Amyloid Positive Subjects over Time
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End point description:

Percentage of amyloid positive subjects over time was reported. Subjects who had Amyloid PET (using Centiloid scales) values greater than or equal to 30.00 were considered as amyloid positive. The OLE PD analysis set was the group of subjects who had sufficient PD data to derive at least 1 PD parameter during the OLE Phase. Here, 'n' refers to number of subjects analyzed at given time points.

End point type	Secondary
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End point timeframe:

OLE Phase: Baseline, at Months 3, 6, 12, 24, 36 and 48

End point values	OLE Phase: Newly Treated Core Placebo	OLE Phase: Re-treated Core Lower Doses	OLE Phase: Re-treated Core 10 mg/kg Monthly	OLE Phase: Re-treated Core 10 mg/kg Biweekly
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	27	20	36	22
Units: percentage of subjects				
number (not applicable)				
Amyloid Positivity at Baseline (n= 27, 20, 36, 22)	92.6	75.0	63.9	22.7
Month 3 (n= 9, 9, 18, 10)	66.7	44.4	44.4	0
Month 6 (n= 11, 7, 11, 10)	45.5	57.1	45.5	20.0
Month 12 (n= 19, 13, 25, 18)	36.8	30.8	40.0	11.1
Month 24 (n= 17, 14, 26, 13)	5.9	21.4	15.4	0
Month 36 (n= 13, 10, 17,9)	15.4	20.0	0	0
Month 48 (n= 9, 7, 12, 8)	0	28.6	0	0

Statistical analyses

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Core Phase: From first dose of the study drug (Week 1) up to 90 days after last dose of study drug (up to 21 months); OLE Phase: From first dose of the study drug (Week 1) up to 30 days after last dose of study drug (up to 61 months)

Adverse event reporting additional description:

Adverse events were collected for all subjects who were in SAS (Core: group of subjects who received at least 1 dose of study drug and had at least 1 post dose safety assessment; OLE: group of subjects who received at least 1 active dose of study drug). MedDRA Version is 20.1 for core and 25.0 for OLE.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	20.1, 25.0

Reporting groups

Reporting group title	Core Study Phase: Placebo
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Reporting group description:

Subjects received lecanemab matching-placebo as 60-minute IV infusions, biweekly or monthly, up to 18 months. Subjects were followed up for 3 months after last dose of lecanemab matched placebo in core study phase.

Reporting group title	Core Study Phase: Lecanemab 2.5 mg/kg Biweekly
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Reporting group description:

Subjects received lecanemab 2.5 mg/kg as 60-minute IV infusions, biweekly, up to 18 months. Subjects were followed up for 3 months after last dose of lecanemab in core study phase.

Reporting group title	Core Study Phase: Lecanemab 5 mg/kg Monthly
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Reporting group description:

Subjects received lecanemab 5 mg/kg as 60-minute IV infusions, monthly, up to 18 months. Subjects were followed up for 3 months after last dose of lecanemab in core study phase.

Reporting group title	Core Study Phase: Lecanemab 5 mg/kg Biweekly
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Reporting group description:

Subjects received lecanemab 5 mg/kg as 60-minute IV infusions, biweekly, up to 18 months. Subjects were followed up for 3 months after last dose of lecanemab in core study phase.

Reporting group title	Core Study Phase: Lecanemab 10 mg/kg Monthly
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Reporting group description:

Subjects received lecanemab 10 mg/kg as 60-minute IV infusions, monthly, up to 18 months. Subjects were followed up for 3 months after last dose of lecanemab in core study phase.

Reporting group title	Core Study Phase: Lecanemab 10 mg/kg Biweekly
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Reporting group description:

Subjects received lecanemab 10 mg/kg as 60-minute IV infusions, biweekly, up to 18 months. Subjects were followed up for 3 months after last dose of lecanemab in core study phase.

Reporting group title	OLE Phase: Lecanemab 10 mg/kg Biweekly
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Reporting group description:

Subjects received lecanemab 10 mg/kg as 60-minute IV infusions, biweekly, up to 60 months. Subjects were followed up for 3 months after last dose of lecanemab in OLE phase.

Serious adverse events	Core Study Phase: Placebo	Core Study Phase: Lecanemab 2.5 mg/kg Biweekly	Core Study Phase: Lecanemab 5 mg/kg Monthly
Total subjects affected by serious adverse events			
subjects affected / exposed	43 / 245 (17.55%)	10 / 52 (19.23%)	4 / 51 (7.84%)

number of deaths (all causes) number of deaths resulting from adverse events	2	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain neoplasm			
subjects affected / exposed	0 / 245 (0.00%)	1 / 52 (1.92%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Hepatocellular carcinoma			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ductal adenocarcinoma of pancreas			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal proliferative breast lesion			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoma			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive ductal breast carcinoma			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			

subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sarcoma			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transitional cell carcinoma			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer metastatic			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma stage III			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuroendocrine carcinoma			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			

subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm of unknown primary site			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Internal haemorrhage			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Axillary vein thrombosis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Cyst			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Fatigue			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral swelling			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulcer haemorrhage			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest discomfort			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			

Vaginal prolapse			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary mass			
subjects affected / exposed	0 / 245 (0.00%)	2 / 52 (3.85%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Aspiration			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemothorax			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Delirium			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Agitation			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aggression			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			

subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic disorder			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device breakage			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood creatinine abnormal			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol poisoning			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Craniocerebral injury			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial bones fracture			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	4 / 245 (1.63%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			

subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaw fracture			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Patella fracture			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic rupture			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord injury			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sternal fracture			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			

subjects affected / exposed	2 / 245 (0.82%)	1 / 52 (1.92%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haemorrhage			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic vertebral fracture			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound dehiscence			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical vertebral fracture			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fractured coccyx			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniofacial fracture			

subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint injury			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural hypotension			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic renal injury			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin laceration			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary contusion			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 245 (0.00%)	1 / 52 (1.92%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			

subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 245 (0.00%)	1 / 52 (1.92%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Bradycardia			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 245 (0.00%)	1 / 52 (1.92%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus bradycardia			

subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus node dysfunction			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress cardiomyopathy			
subjects affected / exposed	0 / 245 (0.00%)	1 / 52 (1.92%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve stenosis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Altered state of consciousness			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amyloid related imaging abnormalities			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aphasia			

subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral artery thrombosis			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral microhaemorrhage			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical radiculopathy			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolic stroke			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Focal dyscognitive seizures			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic transformation stroke			

subjects affected / exposed	0 / 245 (0.00%)	1 / 52 (1.92%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemic seizure			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Normal pressure hydrocephalus			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			

subjects affected / exposed	3 / 245 (1.22%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	2 / 51 (3.92%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amyloid related imaging abnormality-oedema/effusion			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acquired epileptic aphasia			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superficial siderosis of central nervous system			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural hygroma			

subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic encephalopathy			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thalamic infarction			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukopenia			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coagulopathy			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood loss anaemia			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			

Vertigo			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Retinal detachment			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal mass			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Inguinal hernia			
subjects affected / exposed	1 / 245 (0.41%)	1 / 52 (1.92%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal food impaction			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			

subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis acute			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis chronic			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis acute			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus urinary			

subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic kidney disease			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	4 / 245 (1.63%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhabdomyolysis			

subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal stenosis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridial sepsis			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			

subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal sepsis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			

subjects affected / exposed	1 / 245 (0.41%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal infection			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypoglycaemia			

subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Core Study Phase: Lecanemab 5 mg/kg Biweekly	Core Study Phase: Lecanemab 10 mg/kg Monthly	Core Study Phase: Lecanemab 10 mg/kg Biweekly
Total subjects affected by serious adverse events			
subjects affected / exposed	16 / 92 (17.39%)	31 / 253 (12.25%)	25 / 161 (15.53%)
number of deaths (all causes)	1	2	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon			
subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain neoplasm			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatocellular carcinoma			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ductal adenocarcinoma of pancreas			

subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal proliferative breast lesion			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoma			
subjects affected / exposed	1 / 92 (1.09%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sarcoma			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transitional cell carcinoma			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer metastatic			

subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma stage III			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuroendocrine carcinoma			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm of unknown primary site			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Internal haemorrhage			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Axillary vein thrombosis			

subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Cyst			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	1 / 92 (1.09%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 92 (0.00%)	2 / 253 (0.79%)	2 / 161 (1.24%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral swelling			
subjects affected / exposed	1 / 92 (1.09%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulcer haemorrhage			

subjects affected / exposed	1 / 92 (1.09%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest discomfort			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Vaginal prolapse			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	2 / 161 (1.24%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Dyspnoea			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	2 / 161 (1.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary mass			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Aspiration			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemothorax			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			

Delirium			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Agitation			
subjects affected / exposed	1 / 92 (1.09%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aggression			
subjects affected / exposed	1 / 92 (1.09%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination			
subjects affected / exposed	1 / 92 (1.09%)	1 / 253 (0.40%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	1 / 92 (1.09%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic disorder			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	1 / 92 (1.09%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			

Device breakage			
subjects affected / exposed	1 / 92 (1.09%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood creatinine abnormal			
subjects affected / exposed	1 / 92 (1.09%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol poisoning			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniocerebral injury			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial bones fracture			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			
subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Femur fracture			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaw fracture			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Patella fracture			
subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			

subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic rupture			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord injury			
subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Sternal fracture			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haemorrhage			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic vertebral fracture			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound dehiscence			

subjects affected / exposed	1 / 92 (1.09%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical vertebral fracture			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fractured coccyx			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniofacial fracture			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint injury			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural hypotension			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic renal injury			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin laceration			

subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary contusion			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			

subjects affected / exposed	1 / 92 (1.09%)	1 / 253 (0.40%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	1 / 92 (1.09%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus bradycardia			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus node dysfunction			
subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress cardiomyopathy			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve stenosis			

subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Altered state of consciousness			
subjects affected / exposed	1 / 92 (1.09%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amyloid related imaging abnormalities			
subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	3 / 161 (1.86%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aphasia			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral artery thrombosis			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral microhaemorrhage			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	2 / 161 (1.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	1 / 92 (1.09%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical radiculopathy			

subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolic stroke			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Focal dyscognitive seizures			
subjects affected / exposed	1 / 92 (1.09%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic transformation stroke			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed	1 / 92 (1.09%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	1 / 92 (1.09%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemic seizure			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			

subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Normal pressure hydrocephalus			
subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	1 / 92 (1.09%)	1 / 253 (0.40%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amyloid related imaging abnormality-oedema/effusion			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acquired epileptic aphasia			

subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superficial siderosis of central nervous system			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural hygroma			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic encephalopathy			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thalamic infarction			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukopenia			

subjects affected / exposed	1 / 92 (1.09%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Coagulopathy			
subjects affected / exposed	1 / 92 (1.09%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood loss anaemia			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Retinal detachment			
subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Enterocolitis			
subjects affected / exposed	1 / 92 (1.09%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal mass			
subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal food impaction			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			

subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis acute			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis chronic			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	1 / 92 (1.09%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hepatitis acute			

subjects affected / exposed	1 / 92 (1.09%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 92 (1.09%)	0 / 253 (0.00%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus urinary			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic kidney disease			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 92 (1.09%)	0 / 253 (0.00%)	2 / 161 (1.24%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Arthritis			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhabdomyolysis			
subjects affected / exposed	1 / 92 (1.09%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal stenosis			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			

subjects affected / exposed	1 / 92 (1.09%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridial sepsis			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	1 / 92 (1.09%)	1 / 253 (0.40%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 92 (1.09%)	0 / 253 (0.00%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			

subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal sepsis			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 92 (1.09%)	0 / 253 (0.00%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal infection			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			

subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypoglycaemia			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	1 / 161 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	0 / 92 (0.00%)	1 / 253 (0.40%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	OLE Phase: Lecanemab 10 mg/kg Biweekly		
Total subjects affected by serious adverse events			
subjects affected / exposed	60 / 180 (33.33%)		
number of deaths (all causes)	5		
number of deaths resulting from			

adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Brain neoplasm			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatocellular carcinoma			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ductal adenocarcinoma of pancreas			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intraductal proliferative breast lesion			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymphoma			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malignant melanoma			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Prostate cancer				
subjects affected / exposed	0 / 180 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sarcoma				
subjects affected / exposed	0 / 180 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Transitional cell carcinoma				
subjects affected / exposed	1 / 180 (0.56%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Breast cancer metastatic				
subjects affected / exposed	1 / 180 (0.56%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lung adenocarcinoma				
subjects affected / exposed	1 / 180 (0.56%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lung adenocarcinoma stage III				
subjects affected / exposed	1 / 180 (0.56%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Neuroendocrine carcinoma				
subjects affected / exposed	1 / 180 (0.56%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Metastases to central nervous system				
subjects affected / exposed	1 / 180 (0.56%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Malignant neoplasm of unknown primary site				

subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pancreatic carcinoma			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Vascular disorders			
Internal haemorrhage			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Axillary vein thrombosis			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypotension			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Cyst			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chest pain			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Fatigue			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Non-cardiac chest pain			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peripheral swelling			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ulcer haemorrhage			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyrexia			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Asthenia			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Chest discomfort			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Vaginal prolapse			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Benign prostatic hyperplasia			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dyspnoea			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary mass			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory failure			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aspiration			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Haemothorax			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pleural effusion			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumothorax			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Delirium			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Agitation			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aggression			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hallucination			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Suicidal ideation			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychotic disorder			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mental status changes			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Depression			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Product issues			
Device breakage			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
Blood creatinine abnormal			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Alcohol poisoning			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Craniocerebral injury			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Facial bones fracture				
subjects affected / exposed	0 / 180 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fall				
subjects affected / exposed	7 / 180 (3.89%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Femoral neck fracture				
subjects affected / exposed	0 / 180 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Femur fracture				
subjects affected / exposed	1 / 180 (0.56%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hip fracture				
subjects affected / exposed	2 / 180 (1.11%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Humerus fracture				
subjects affected / exposed	0 / 180 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pelvic fracture				
subjects affected / exposed	2 / 180 (1.11%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Infusion related reaction				
subjects affected / exposed	1 / 180 (0.56%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Jaw fracture				

subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Patella fracture			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post procedural haemorrhage			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rib fracture			
subjects affected / exposed	3 / 180 (1.67%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Splenic rupture			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal cord injury			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sternal fracture			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subdural haematoma			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Subdural haemorrhage			

subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Thoracic vertebral fracture			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper limb fracture			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wound dehiscence			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cervical vertebral fracture			
subjects affected / exposed	3 / 180 (1.67%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 1		
Head injury			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fractured coccyx			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Craniofacial fracture			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Joint injury			

subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Post procedural hypotension			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Traumatic renal injury			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin laceration			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pulmonary contusion			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Angina unstable			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Angina pectoris			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac arrest			

subjects affected / exposed	0 / 180 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bradycardia				
subjects affected / exposed	0 / 180 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrioventricular block complete				
subjects affected / exposed	0 / 180 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure congestive				
subjects affected / exposed	0 / 180 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coronary artery disease				
subjects affected / exposed	1 / 180 (0.56%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Coronary artery stenosis				
subjects affected / exposed	0 / 180 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myocardial infarction				
subjects affected / exposed	2 / 180 (1.11%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Sinus bradycardia				
subjects affected / exposed	0 / 180 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sinus node dysfunction				

subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Stress cardiomyopathy			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ventricular tachycardia			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aortic valve stenosis			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arrhythmia			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Nervous system disorders			
Altered state of consciousness			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Amyloid related imaging abnormalities			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aphasia			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral artery thrombosis			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral microhaemorrhage			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular accident			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cervical radiculopathy			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dizziness			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Embolic stroke			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Focal dyscognitive seizures			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemorrhagic transformation stroke			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolic encephalopathy			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ischaemic stroke			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoglycaemic seizure			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Headache			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Presyncope			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Normal pressure hydrocephalus			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Seizure			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Syncope			
subjects affected / exposed	3 / 180 (1.67%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Transient ischaemic attack			

subjects affected / exposed	4 / 180 (2.22%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Cerebral haemorrhage				
subjects affected / exposed	1 / 180 (0.56%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Amyloid related imaging abnormality-oedema/effusion				
subjects affected / exposed	2 / 180 (1.11%)			
occurrences causally related to treatment / all	2 / 2			
deaths causally related to treatment / all	0 / 0			
Acquired epileptic aphasia				
subjects affected / exposed	1 / 180 (0.56%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cerebral infarction				
subjects affected / exposed	2 / 180 (1.11%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Generalised tonic-clonic seizure				
subjects affected / exposed	1 / 180 (0.56%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Superficial siderosis of central nervous system				
subjects affected / exposed	1 / 180 (0.56%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Subdural hygroma				
subjects affected / exposed	1 / 180 (0.56%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Toxic encephalopathy				

subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Thalamic infarction			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Leukopenia			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coagulopathy			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancytopenia			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood loss anaemia			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Eye disorders			

Retinal detachment			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colitis			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Enterocolitis			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intestinal obstruction			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intestinal mass			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Inguinal hernia			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oesophageal food impaction			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Ascites			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Constipation			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Small intestinal obstruction			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pancreatitis acute			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nausea			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholangitis acute			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholecystitis chronic			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatic failure			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatitis acute			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	3 / 180 (1.67%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Nephrolithiasis			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary retention			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Calculus urinary			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Chronic kidney disease			

subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haematuria			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arthritis			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Back pain			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intervertebral disc protrusion			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteoarthritis			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rhabdomyolysis			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal stenosis			

subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rotator cuff syndrome			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Cellulitis			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bacteraemia			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Appendicitis			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Clostridial sepsis			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Clostridium difficile colitis			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Clostridium difficile infection			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Influenza			

subjects affected / exposed	0 / 180 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticulitis				
subjects affected / exposed	0 / 180 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	4 / 180 (2.22%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	3 / 180 (1.67%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Upper respiratory tract infection				
subjects affected / exposed	0 / 180 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Streptococcal sepsis				
subjects affected / exposed	0 / 180 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	0 / 180 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urosepsis				
subjects affected / exposed	0 / 180 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abdominal infection				

subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
COVID-19			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Osteomyelitis			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Septic shock			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia aspiration			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Hypoglycaemia			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypernatraemia			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dehydration			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Core Study Phase: Placebo	Core Study Phase: Lecanemab 2.5 mg/kg Biweekly	Core Study Phase: Lecanemab 5 mg/kg Monthly
Total subjects affected by non-serious adverse events			
subjects affected / exposed	212 / 245 (86.53%)	46 / 52 (88.46%)	48 / 51 (94.12%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Squamous cell carcinoma of skin			
subjects affected / exposed	4 / 245 (1.63%)	3 / 52 (5.77%)	1 / 51 (1.96%)
occurrences (all)	5	3	3
Basal cell carcinoma			
subjects affected / exposed	7 / 245 (2.86%)	4 / 52 (7.69%)	2 / 51 (3.92%)
occurrences (all)	12	4	2
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	28 / 245 (11.43%)	3 / 52 (5.77%)	6 / 51 (11.76%)
occurrences (all)	40	3	10
Contusion			
subjects affected / exposed	7 / 245 (2.86%)	2 / 52 (3.85%)	5 / 51 (9.80%)
occurrences (all)	7	2	6
Infusion related reaction			
subjects affected / exposed	8 / 245 (3.27%)	3 / 52 (5.77%)	4 / 51 (7.84%)
occurrences (all)	12	3	5
Skin laceration			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			

subjects affected / exposed occurrences (all)	8 / 245 (3.27%) 8	0 / 52 (0.00%) 0	1 / 51 (1.96%) 1
Procedural pain subjects affected / exposed occurrences (all)	4 / 245 (1.63%) 7	3 / 52 (5.77%) 3	2 / 51 (3.92%) 3
Vascular disorders			
Hypertension subjects affected / exposed occurrences (all)	13 / 245 (5.31%) 13	1 / 52 (1.92%) 1	1 / 51 (1.96%) 1
Hypotension subjects affected / exposed occurrences (all)	5 / 245 (2.04%) 5	2 / 52 (3.85%) 2	3 / 51 (5.88%) 3
Nervous system disorders			
Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits subjects affected / exposed occurrences (all)	0 / 245 (0.00%) 0	0 / 52 (0.00%) 0	0 / 51 (0.00%) 0
Amyloid related imaging abnormality-oedema/effusion subjects affected / exposed occurrences (all)	0 / 245 (0.00%) 0	0 / 52 (0.00%) 0	0 / 51 (0.00%) 0
Dizziness subjects affected / exposed occurrences (all)	18 / 245 (7.35%) 19	4 / 52 (7.69%) 5	0 / 51 (0.00%) 0
Superficial siderosis of central nervous system subjects affected / exposed occurrences (all)	1 / 245 (0.41%) 1	0 / 52 (0.00%) 0	1 / 51 (1.96%) 1
Cerebral microhaemorrhage subjects affected / exposed occurrences (all)	12 / 245 (4.90%) 16	2 / 52 (3.85%) 2	7 / 51 (13.73%) 10
Amyloid related imaging abnormalities subjects affected / exposed occurrences (all)	2 / 245 (0.82%) 2	1 / 52 (1.92%) 1	1 / 51 (1.96%) 1
Headache subjects affected / exposed occurrences (all)	25 / 245 (10.20%) 34	9 / 52 (17.31%) 12	4 / 51 (7.84%) 5

Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	15 / 245 (6.12%)	4 / 52 (7.69%)	1 / 51 (1.96%)
occurrences (all)	39	5	1
Pyrexia			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	12 / 245 (4.90%)	5 / 52 (9.62%)	7 / 51 (13.73%)
occurrences (all)	14	6	8
Nausea			
subjects affected / exposed	10 / 245 (4.08%)	1 / 52 (1.92%)	4 / 51 (7.84%)
occurrences (all)	14	1	6
Vomiting			
subjects affected / exposed	8 / 245 (3.27%)	2 / 52 (3.85%)	4 / 51 (7.84%)
occurrences (all)	14	3	5
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	12 / 245 (4.90%)	1 / 52 (1.92%)	2 / 51 (3.92%)
occurrences (all)	13	2	3
Skin and subcutaneous tissue disorders			
Drug eruption			
subjects affected / exposed	1 / 245 (0.41%)	3 / 52 (5.77%)	0 / 51 (0.00%)
occurrences (all)	1	3	0
Erythema			
subjects affected / exposed	2 / 245 (0.82%)	0 / 52 (0.00%)	3 / 51 (5.88%)
occurrences (all)	2	0	3
Psychiatric disorders			

Depression			
subjects affected / exposed	13 / 245 (5.31%)	1 / 52 (1.92%)	3 / 51 (5.88%)
occurrences (all)	13	1	3
Agitation			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	7 / 245 (2.86%)	3 / 52 (5.77%)	3 / 51 (5.88%)
occurrences (all)	7	3	4
Anxiety			
subjects affected / exposed	15 / 245 (6.12%)	1 / 52 (1.92%)	3 / 51 (5.88%)
occurrences (all)	20	1	3
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	17 / 245 (6.94%)	0 / 52 (0.00%)	4 / 51 (7.84%)
occurrences (all)	19	0	4
Back pain			
subjects affected / exposed	24 / 245 (9.80%)	4 / 52 (7.69%)	6 / 51 (11.76%)
occurrences (all)	26	4	6
Pain in extremity			
subjects affected / exposed	10 / 245 (4.08%)	1 / 52 (1.92%)	2 / 51 (3.92%)
occurrences (all)	10	1	2
Muscle spasms			
subjects affected / exposed	5 / 245 (2.04%)	1 / 52 (1.92%)	6 / 51 (11.76%)
occurrences (all)	5	2	7
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 245 (0.00%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	15 / 245 (6.12%)	0 / 52 (0.00%)	0 / 51 (0.00%)
occurrences (all)	15	0	0
Nasopharyngitis			
subjects affected / exposed	28 / 245 (11.43%)	3 / 52 (5.77%)	7 / 51 (13.73%)
occurrences (all)	33	4	10
Urinary tract infection			

subjects affected / exposed	32 / 245 (13.06%)	5 / 52 (9.62%)	5 / 51 (9.80%)
occurrences (all)	39	6	6
Sinusitis			
subjects affected / exposed	8 / 245 (3.27%)	1 / 52 (1.92%)	5 / 51 (9.80%)
occurrences (all)	9	1	8
Upper respiratory tract infection			
subjects affected / exposed	41 / 245 (16.73%)	7 / 52 (13.46%)	7 / 51 (13.73%)
occurrences (all)	52	7	9

Non-serious adverse events	Core Study Phase: Lecanemab 5 mg/kg Biweekly	Core Study Phase: Lecanemab 10 mg/kg Monthly	Core Study Phase: Lecanemab 10 mg/kg Biweekly
Total subjects affected by non-serious adverse events			
subjects affected / exposed	80 / 92 (86.96%)	237 / 253 (93.68%)	135 / 161 (83.85%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Squamous cell carcinoma of skin			
subjects affected / exposed	2 / 92 (2.17%)	3 / 253 (1.19%)	1 / 161 (0.62%)
occurrences (all)	2	3	1
Basal cell carcinoma			
subjects affected / exposed	6 / 92 (6.52%)	4 / 253 (1.58%)	3 / 161 (1.86%)
occurrences (all)	8	5	5
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	13 / 92 (14.13%)	21 / 253 (8.30%)	17 / 161 (10.56%)
occurrences (all)	20	26	21
Contusion			
subjects affected / exposed	6 / 92 (6.52%)	11 / 253 (4.35%)	7 / 161 (4.35%)
occurrences (all)	9	13	8
Infusion related reaction			
subjects affected / exposed	11 / 92 (11.96%)	59 / 253 (23.32%)	31 / 161 (19.25%)
occurrences (all)	16	111	44
Skin laceration			
subjects affected / exposed	0 / 92 (0.00%)	0 / 253 (0.00%)	0 / 161 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	1 / 92 (1.09%)	13 / 253 (5.14%)	4 / 161 (2.48%)
occurrences (all)	1	16	4

Procedural pain subjects affected / exposed occurrences (all)	2 / 92 (2.17%) 2	4 / 253 (1.58%) 4	4 / 161 (2.48%) 4
Vascular disorders			
Hypertension subjects affected / exposed occurrences (all)	3 / 92 (3.26%) 5	10 / 253 (3.95%) 10	7 / 161 (4.35%) 7
Hypotension subjects affected / exposed occurrences (all)	2 / 92 (2.17%) 3	5 / 253 (1.98%) 5	2 / 161 (1.24%) 2
Nervous system disorders			
Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits subjects affected / exposed occurrences (all)	0 / 92 (0.00%) 0	0 / 253 (0.00%) 0	0 / 161 (0.00%) 0
Amyloid related imaging abnormality-oedema/effusion subjects affected / exposed occurrences (all)	0 / 92 (0.00%) 0	0 / 253 (0.00%) 0	0 / 161 (0.00%) 0
Dizziness subjects affected / exposed occurrences (all)	10 / 92 (10.87%) 12	9 / 253 (3.56%) 10	13 / 161 (8.07%) 18
Superficial siderosis of central nervous system subjects affected / exposed occurrences (all)	5 / 92 (5.43%) 6	7 / 253 (2.77%) 8	1 / 161 (0.62%) 1
Cerebral microhaemorrhage subjects affected / exposed occurrences (all)	12 / 92 (13.04%) 14	22 / 253 (8.70%) 30	9 / 161 (5.59%) 12
Amyloid related imaging abnormalities subjects affected / exposed occurrences (all)	3 / 92 (3.26%) 3	24 / 253 (9.49%) 24	13 / 161 (8.07%) 13
Headache subjects affected / exposed occurrences (all)	17 / 92 (18.48%) 24	43 / 253 (17.00%) 58	23 / 161 (14.29%) 34
Blood and lymphatic system disorders			

Anaemia subjects affected / exposed occurrences (all)	0 / 92 (0.00%) 0	0 / 253 (0.00%) 0	0 / 161 (0.00%) 0
General disorders and administration site conditions Fatigue subjects affected / exposed occurrences (all) Pyrexia subjects affected / exposed occurrences (all)	7 / 92 (7.61%) 8 0 / 92 (0.00%) 0	17 / 253 (6.72%) 22 0 / 253 (0.00%) 0	8 / 161 (4.97%) 14 0 / 161 (0.00%) 0
Gastrointestinal disorders Constipation subjects affected / exposed occurrences (all) Diarrhoea subjects affected / exposed occurrences (all) Nausea subjects affected / exposed occurrences (all) Vomiting subjects affected / exposed occurrences (all)	0 / 92 (0.00%) 0 12 / 92 (13.04%) 12 8 / 92 (8.70%) 20 7 / 92 (7.61%) 15	0 / 253 (0.00%) 0 16 / 253 (6.32%) 22 15 / 253 (5.93%) 25 10 / 253 (3.95%) 11	0 / 161 (0.00%) 0 12 / 161 (7.45%) 17 6 / 161 (3.73%) 6 2 / 161 (1.24%) 2
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	4 / 92 (4.35%) 6	11 / 253 (4.35%) 13	14 / 161 (8.70%) 16
Skin and subcutaneous tissue disorders Drug eruption subjects affected / exposed occurrences (all) Erythema subjects affected / exposed occurrences (all)	2 / 92 (2.17%) 2 1 / 92 (1.09%) 1	4 / 253 (1.58%) 5 1 / 253 (0.40%) 1	1 / 161 (0.62%) 1 1 / 161 (0.62%) 1
Psychiatric disorders			

Depression subjects affected / exposed occurrences (all)	6 / 92 (6.52%) 7	13 / 253 (5.14%) 14	5 / 161 (3.11%) 5
Agitation subjects affected / exposed occurrences (all)	0 / 92 (0.00%) 0	0 / 253 (0.00%) 0	0 / 161 (0.00%) 0
Insomnia subjects affected / exposed occurrences (all)	3 / 92 (3.26%) 3	7 / 253 (2.77%) 7	2 / 161 (1.24%) 2
Anxiety subjects affected / exposed occurrences (all)	4 / 92 (4.35%) 4	10 / 253 (3.95%) 11	6 / 161 (3.73%) 6
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	5 / 92 (5.43%) 6	12 / 253 (4.74%) 12	6 / 161 (3.73%) 6
Back pain subjects affected / exposed occurrences (all)	4 / 92 (4.35%) 4	20 / 253 (7.91%) 21	11 / 161 (6.83%) 11
Pain in extremity subjects affected / exposed occurrences (all)	7 / 92 (7.61%) 7	8 / 253 (3.16%) 8	3 / 161 (1.86%) 3
Muscle spasms subjects affected / exposed occurrences (all)	0 / 92 (0.00%) 0	5 / 253 (1.98%) 5	3 / 161 (1.86%) 3
Infections and infestations			
COVID-19 subjects affected / exposed occurrences (all)	0 / 92 (0.00%) 0	0 / 253 (0.00%) 0	0 / 161 (0.00%) 0
Bronchitis subjects affected / exposed occurrences (all)	2 / 92 (2.17%) 2	9 / 253 (3.56%) 10	4 / 161 (2.48%) 7
Nasopharyngitis subjects affected / exposed occurrences (all)	9 / 92 (9.78%) 15	19 / 253 (7.51%) 21	13 / 161 (8.07%) 19
Urinary tract infection			

subjects affected / exposed	17 / 92 (18.48%)	25 / 253 (9.88%)	16 / 161 (9.94%)
occurrences (all)	26	35	21
Sinusitis			
subjects affected / exposed	1 / 92 (1.09%)	9 / 253 (3.56%)	7 / 161 (4.35%)
occurrences (all)	1	14	7
Upper respiratory tract infection			
subjects affected / exposed	10 / 92 (10.87%)	22 / 253 (8.70%)	19 / 161 (11.80%)
occurrences (all)	11	24	22

Non-serious adverse events	OLE Phase: Lecanemab 10 mg/kg Biweekly		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	169 / 180 (93.89%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
Basal cell carcinoma			
subjects affected / exposed	12 / 180 (6.67%)		
occurrences (all)	16		
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	47 / 180 (26.11%)		
occurrences (all)	82		
Contusion			
subjects affected / exposed	18 / 180 (10.00%)		
occurrences (all)	20		
Infusion related reaction			
subjects affected / exposed	39 / 180 (21.67%)		
occurrences (all)	98		
Skin laceration			
subjects affected / exposed	12 / 180 (6.67%)		
occurrences (all)	14		
Skin abrasion			
subjects affected / exposed	11 / 180 (6.11%)		
occurrences (all)	11		

Procedural pain subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0		
Vascular disorders			
Hypertension subjects affected / exposed occurrences (all)	18 / 180 (10.00%) 25		
Hypotension subjects affected / exposed occurrences (all)	11 / 180 (6.11%) 15		
Nervous system disorders			
Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits subjects affected / exposed occurrences (all)	30 / 180 (16.67%) 49		
Amyloid related imaging abnormality-oedema/effusion subjects affected / exposed occurrences (all)	15 / 180 (8.33%) 30		
Dizziness subjects affected / exposed occurrences (all)	15 / 180 (8.33%) 17		
Superficial siderosis of central nervous system subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0		
Cerebral microhaemorrhage subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0		
Amyloid related imaging abnormalities subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0		
Headache subjects affected / exposed occurrences (all)	17 / 180 (9.44%) 18		
Blood and lymphatic system disorders			

Anaemia subjects affected / exposed occurrences (all)	10 / 180 (5.56%) 10		
General disorders and administration site conditions Fatigue subjects affected / exposed occurrences (all) Pyrexia subjects affected / exposed occurrences (all)	9 / 180 (5.00%) 10 11 / 180 (6.11%) 25		
Gastrointestinal disorders Constipation subjects affected / exposed occurrences (all) Diarrhoea subjects affected / exposed occurrences (all) Nausea subjects affected / exposed occurrences (all) Vomiting subjects affected / exposed occurrences (all)	9 / 180 (5.00%) 11 11 / 180 (6.11%) 14 12 / 180 (6.67%) 13 11 / 180 (6.11%) 16		
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	12 / 180 (6.67%) 24		
Skin and subcutaneous tissue disorders Drug eruption subjects affected / exposed occurrences (all) Erythema subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0 0 / 180 (0.00%) 0		
Psychiatric disorders			

Depression			
subjects affected / exposed	11 / 180 (6.11%)		
occurrences (all)	11		
Agitation			
subjects affected / exposed	12 / 180 (6.67%)		
occurrences (all)	12		
Insomnia			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
Anxiety			
subjects affected / exposed	20 / 180 (11.11%)		
occurrences (all)	21		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	19 / 180 (10.56%)		
occurrences (all)	21		
Back pain			
subjects affected / exposed	18 / 180 (10.00%)		
occurrences (all)	19		
Pain in extremity			
subjects affected / exposed	9 / 180 (5.00%)		
occurrences (all)	10		
Muscle spasms			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
Infections and infestations			
COVID-19			
subjects affected / exposed	33 / 180 (18.33%)		
occurrences (all)	36		
Bronchitis			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
Nasopharyngitis			
subjects affected / exposed	22 / 180 (12.22%)		
occurrences (all)	32		
Urinary tract infection			

subjects affected / exposed	34 / 180 (18.89%)		
occurrences (all)	49		
Sinusitis			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
Upper respiratory tract infection			
subjects affected / exposed	18 / 180 (10.00%)		
occurrences (all)	27		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
22 April 2013	<p>Amendment 1: For consistency to align with NIA-AA terminology, mild "Alzheimer's" dementia was changed to mild "Alzheimer's disease dementia". • Clarified that all 3 clinical scales were to be assessed before diagnosis and to further clarify the role of Wechsler Memory Scale criteria in eligibility (for MCI due to AD only). • Clarified Inclusion Criterion 4 for MCI due to AD subjects with objective impairment in episodic memory according to Wechsler Memory Scale. Subjects who scored below the age-adjusted range (not above) were also eligible, and thus the Inclusion Criterion for MCI due to AD was revised to clarify this point. • Clarified exclusion criterion No. 11 regarding thyroid function, in order to enable subjects who were euthyroid, and otherwise well and suitable for the study, to be eligible. • Updated the definition of futility and how it was addressed. • Included sensitivity analyses for the primary endpoint, so to include analyses that did not censor data based on compliance or changes in medication for AD. • Revised prohibited concomitant medication criteria window from before Screening to before Baseline, so to allow subjects additional time to meet the criteria for concomitant medication. • Scheduled infusion window was increased from 3 to 8 days, so to minimize the number of missed infusions while still ensuring adequate exposure to study drug. • Clarified that the GDS was clinician-assisted. While subjects can usually report this information on their own, it was important to clarify that the instrument would be clinician-assisted in the event that a subject was not capable of self-reporting. • Clarification on collection of exploratory biomarker and pharmacogenomic samples, since exploratory biomarker and pharmacogenomic samples would not be collected in those countries whose local regulations require the return of these data to subjects.</p>
27 June 2013	<p>Amendment 2: Amyvid could now be used in the EU, as had been recently approved. • The imaging subgroup was comprised of subjects in the United States only, since it was anticipated relatively few subjects were imaged with Amyvid in the EU, so for consistency, only those subjects in the United States were in the imaging subgroup.</p>
18 September 2013	<p>Amendment 3: As requested by the Germany regulatory authorities through the VHP, home infusions were not to be allowed at study sites in Germany. • As requested by EU regulatory authorities through the VHP process, for study inclusion, MMSE scores had to be greater than or equal to 22 or less than or equal to 28 in France, Germany, Spain, Sweden, Netherlands, and United Kingdom.</p>
09 July 2014	<p>Amendment 4: As recommended by the DSMB, to allow for early detection of ARIA-E before the Visit 9 (Week 13) MRI scan, safety and vMRIs at Visit 7 (Week 9) were added. This measure was to prevent the further dosing of subjects with early ARIA-E • As recommended by the DSMB, after unblinded review of all asymptomatic and symptomatic cases of ARIA-E in Study 201, the randomization algorithm was modified so ApoE4 homozygous subjects were not randomized to BAN2401 10 mg/kg biweekly.</p>
11 August 2014	<p>Amendment 5: Further to Amendment 04, the VHP committee requested that subjects confirmed ApoE4 carriers (homozygous or heterozygous) were not to be randomized to the 10 mg/kg biweekly dose of BAN2401.</p>

20 November 2014	<p>Amendment 6: Since mild AD dementia subjects should also exhibit deficits in episodic memory to be eligible for the study, the inclusion criteria for WMS was revised to apply to all subjects, not only subjects with MCI due to AD. • Since positive amyloid load can be indicated by either PET or CSF Aβ(1-42), CSF was added as an eligibility criterion for amyloid load in the brain to allow for potential study expansion to sites and countries that might not have amyloid PET imaging capabilities. Subjects who consented to both amyloid PET and CSF subgroups needed a positive amyloid result in only 1 of the 2 measures. • Per the Netherlands' request via the VHP process, the inclusion criteria were revised to include subjects with a BMI of greater than 17 kg/m². • Only subjects with hypothyroidism as indicated by elevated TSH were to be excluded. Other tests of thyroid function with results outside the normal range were only to be exclusionary if considered clinically significant by the investigator. • To allow continuous monitoring of the risk factors for development of ARIA unblinding of all subjects who underwent Early Termination due to ARIA was allowed. • To allow for the use of alternative imaging agents and options when the need arose, but maintaining consistency for the quantitative longitudinal assessment, any approved imaging agent could be used in the US, Canada, EU, or any region in which the study was conducted. • In those subjects consenting to CSF collection, CSF collection was moved to coincide to 2 to 4 days after the last visit at which study drug was administered at Visit 29 (Week 53; Month 12). This change allowed for collection of BAN2401 PK in CSF following dosing and coincided with the CSF C_{max}. • So that CSF could be collected predose to determine C_{min} for BAN2401 in CSF, the CSF collection was moved from Visit 42 to Visit 41. Serum PK samples were collected immediately after CSF sampling at Visit 29 and Visit 41.</p>
26 June 2015	<p>Amendment 7: In order to explore preliminary data in Japanese subjects for consistency of treatment effect between populations, 40 randomized Japanese subjects were to be enrolled. • Inclusion Criterion No. 7 was revised to specify that subjects must consent to both Baseline CSF and PET before the eligibility results for either subgroup study were confirmed. • Inclusion Criterion No. 16 was revised to account for subjects with EAD who may lack capacity to consent at Screening, and who had capacity to consent at Screening but may lose capacity to consent over time. • Since potential untoward effects were sufficiently characterized to allow safe flexibility, subjects were no longer required to remain in clinic for 2 hours following infusion at all visits. • Due to low participation in home infusion this option was stopped for subjects recruited after implementation of Amendment 07. However, subjects previously enrolled in the study who had opted for home infusions were allowed to continue with them. • Due to increased availability of approved agents in other regions, the amyloid PET substudy was expanded to outside the US. • To account for the enrollment rate, the overall duration of study was increased from 41 to 67 months with an approximate study end of June 2018. • To increase the statistical power and increase likelihood of detecting an effect on amyloid, the imaging substudy sample size was increased from 260 to 306 subjects.</p>
30 July 2015	<p>Amendment 7: Per request from European Regulatory Authorities a Visit 6 (Week 7) safety MRI was added for European sites only (this safety MRI is not accompanied by vMRI sequences).</p>
19 February 2016	<p>Amendment 8: A 60-month open-label Extension Phase was added, to be conducted only if early success was achieved at any interim analysis or at the Bayesian analysis at 12 months of treatment. The criterion for conducting this open-label Extension Phase was not met, and thus it was not implemented. However, subsequently a 24-month open-label Extension Phase was implemented (see Amendment 11, 14 Sep 2018). • Historical brain amyloid positive PET scans could be used for study eligibility upon evaluation by the central imaging CRO. However, historical PET scans were not to be used as Baseline scans for longitudinal assessments in the imaging subgroup. • BAN2401 had to be infused with a terminal in-line filter. • Skin rash due to study drug was to be considered an event of interest and subjects with skin rash need not be withdrawn from the study.</p>

09 November 2017	Amendment 9: Key secondary objectives and endpoints were specified. • The Bayesian analysis of ADCOMS was extended to include the 18-month endpoint to aid identification of the simplest dose regimen with the highest predictive probability of being the ED90 dose. • It was also specified that the conventional analysis for change from Baseline in ADCOMS at 18 months was based on the ED90 dose identified from the 18-month Bayesian analysis.
16 March 2018	Amendment 10: Updated key secondary objectives and secondary objectives to emphasize disease pathophysiology based on 18-month data. • Updated analysis methods to account for the lack of ApoE4 carriers in the 10 mg/kg biweekly dose group due to the change in the middle of randomization following a Regulatory request by European Health Authorities in July 2014 (see Amendments 04 and 05).
14 September 2018	Amendment 11: An open-label Extension Phase was initiated following the Core Study to allow subjects to receive open-label BAN2401 10 mg/kg biweekly for up to 24 months (2 years), until the drug was commercially available in the country where the subject resided, or until the benefit to risk ratio from treatment with BAN2401 was no longer considered favorable, whichever came first. • Florbetapir was the sole imaging agent used in the open-label Extension Phase PET substudy. As the availability of florbetapir was limited outside of the United States and Japan, the open-label Extension Phase PET was performed in the United States and Japan only using florbetapir and only in subjects who had agreed to participate in the longitudinal PET substudy. • The CSF biomarker exploratory objective and endpoint was removed because of projected lack of enrollment in the substudy. • The drug product formulation was clarified because the current formulation of the drug product was being progressively phased out as stocks neared the end of their shelf life, to be replaced by a newer formulation. • All subjects in the open-label Extension Phase were to receive open-label BAN2401 10 mg/kg biweekly, and it was clarified that the DSMB was to monitor safety only in the Core Study. • The PK sampling times were updated in line with the early timepoint assessments in the open-label Extension Phase. • The clinical experience with BAN2401 was updated to reflect completed and ongoing study data.
15 November 2018	Amendment 12: The requirements for Baseline amyloid PET scan before dosing in the Extension Phase were revised. • Revised tracers for PET longitudinal substudy; revised PET longitudinal substudy assessment timing for subjects in Japan. • Modification of assessment of ARIA-H and ARIA-E. • The Extension Phase inclusion and exclusion criteria were updated. • Revised Extension Phase screening criteria for MRI assessment. • Revised concomitant medications.
15 November 2018	Amendment 13: Modification of the safety monitoring plan for ARIA-E at Japan sites only, based on consultation meeting with Pharmaceuticals and Medical Devices Agency in December 2018.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported