Clinical trial results:
A 24-Month, Phase 3, Multicenter, Placebo-Controlled Study of Efficacy and Safety of Solanezumab versus Placebo in Prodromal Alzheimer's Disease

Summary

EudraCT number	2016-000108-27
Trial protocol	BE PL DE NL GB ES
Global end of trial date	08 May 2017

Results information

Result version number	v1 (current)
This version publication date	24 May 2018
First version publication date	24 May 2018

Trial information

Trial identification

Sponsor protocol code	H8A-MC-LZBE

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02760602
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 16349

Notes:

Sponsors

Sponsor organisation name	Eli Lilly and Company
Sponsor organisation address	Lilly Corporate Center, Indianapolis, IN, United States, 46285
Public contact	Available Mon Fri 9 AM 5 PM EST, Eli Lilly and Company, 1 877CTLilly, clinicaltrials.gov@lilly.com
Scientific contact	Available Mon Fri 9 AM 5 PM EST, Eli Lilly and Company, 1 8772854559, clinicaltrials.gov@lilly.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	08 May 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	08 May 2017
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The main purpose of this study is to investigate the safety and efficacy of the study drug solanezumab in participants with prodromal Alzheimer's disease (AD).

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonization (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which a study is conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	27 June 2016
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: 1
Country: Number of subjects enrolled	Japan: 2
Country: Number of subjects enrolled	Poland: 2
Country: Number of subjects enrolled	United States: 21
Worldwide total number of subjects	26
EEA total number of subjects	2

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)	2
From 65 to 84 years	24

85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Participants were randomized by site and by use of florbetapir positron emission tomography (PET) scanning or cerebrospinal fluid (CSF) for study eligibility.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer

Arms

Are arms mutually exclusive?	Yes
Arm title	Solanezumab

Arm description:

Solanezumab given intravenously (IV) once every 4 weeks for up to 2 years.

Arm type	Experimental
Investigational medicinal product name	Solanezumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Solanezumab 400 milligram (mg) given IV once every 4 weeks for up to 2 years.

Arm title	Placebo

Arm description:

Placebo given IV once every 4 weeks for up to 2 years.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Placebo given IV once every 4 weeks for up to 2 years.

Number of subjects in period 1	Solanezumab	Placebo
Started	13	13
Completed	0	0
Not completed	13	13
Consent withdrawn by subject	1	-

Terminated by sponsor	12	13

Baseline characteristics

Reporting groups	
Reporting group title	Solanezumab
Reporting group description:	
Solanezumab given intravenously (IV) once every 4 weeks for up to 2 years.	
Reporting group title	Placebo
Reporting group description:	
Placebo given IV once every 4 weeks for up to 2 years.	

Reporting group values	Solanezumab	Placebo	Total
Number of subjects	13	13	26
Age categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	73.46	75.62	
standard deviation	± 6.01	± 4.93	-
Gender categorical Units: Subjects			
Female	4	6	10
Male	9	7	16
Sex: Female, Male Units: Subjects			
Female	4	6	10
Male	9	7	16
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	12	13	25
Unknown or Not Reported	1	0	1
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	3	0	3
Native Hawaiian or Other Pacific Islander	1	0	1
Black or African American	0	1	1
White	9	12	21
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Region of Enrollment Units: Subjects			
United States	10	11	21
Japan	2	0	2
Canada	1	0	1
Poland	0	2	2

ADAS-Cog14 at Baseline			
Units: units on a scale			
arithmetic mean	24.08	27.77	
standard deviation	± 8.00	± 3.63	-

End points

End points reporting groups

Reporting group title	Solanezumab
Reporting group description:	
Solanezumab given intravenously (IV) once every 4 weeks for up to 2 years.	
Reporting group title	Placebo
Reporting group description:	
Placebo given IV once every 4 weeks for up to 2 years.	

Primary: Change from Baseline in Alzheimer´s Disease Assessment Scale- Cognitive Subscale (ADAS-Cog14) Score

End point title	Change from Baseline in Alzheimer´s Disease Assessment Scale- Cognitive Subscale (ADAS-Cog14) Score[1]
End point description:	
ADAS-Cog14 is ADAS-Cog11 augmented with orientation, verbal memory, language, praxis, delayed free recall, digit cancellation, and maze-completion measures. The ADAS-Cog14 scale ranges from 0 to 90. Higher scores indicate greater disease severity.	
End point type	Primary
End point timeframe:	
Baseline, 24 Months	

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: Zero participants were analyzed due to trial termination. Therefore, no inferential statistics were planned or conducted for this endpoint.

End point values	Solanezumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[2]	0[3]		
Units: Not Applicable (NA)				

Notes:

[2] - Zero participants were analyzed due to trial termination.

[3] - Zero participants were analyzed due to trial termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline on Alzheimer´s Disease Cooperative Study-Activities of Daily Living Scale for Mild Cognitive Impairment (ADCS-MCI-ADL)

End point title	Change from Baseline on Alzheimer´s Disease Cooperative Study-Activities of Daily Living Scale for Mild Cognitive Impairment (ADCS-MCI-ADL)
End point description:	
The ADCS-MCI-ADL is a functional evaluation scale for MCI patients, based on information provided by an informant that describes the performance of participants in several ADLs. Total score ranges from 0 to 69; lower score indicates greater disease severity.	
End point type	Secondary
End point timeframe:	
Baseline, 24 Months	

End point values	Solanezumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[4]	0[5]		
Units: NA				

Notes:

[4] - Zero participants were analyzed due to trial termination.

[5] - Zero participants were analyzed due to trial termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline on the Mini Mental Status Examination (MMSE)

End point title	Change from Baseline on the Mini Mental Status Examination (MMSE)

End point description:

MMSE is a brief screening instrument used to assess cognitive function (orientation, memory, attention, ability to name objects, follow verbal/written commands, write a sentence, and copy figures) in elderly participants.Total score ranges from 0 to 30; lower score indicates greater disease severity.

End point type	Secondary

End point timeframe:

Baseline, 24 Months

End point values	Solanezumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[6]	0[7]		
Units: NA				

Notes:

[6] - Zero participants were analyzed due to trial termination.

[7] - Zero participants were analyzed due to trial termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline on the Montreal Cognitive Assessment (MoCA)

End point title	Change from Baseline on the Montreal Cognitive Assessment (MoCA)

End point description:

The MoCA will be used as the global cognitive screening instrument. It will also be administered in the clinical trial at baseline and the final visits of each phase as a secondary outcome measure of global cognition. Scores on the MoCA range from 0-30 with 26-30 indicating normal global cognition.

End point type	Secondary

End point timeframe:

Baseline, 24 Months

End point values	Solanezumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[8]	0[9]		
Units: NA				

Notes:

[8] - Zero participants were analyzed due to trial termination.

[9] - Zero participants were analyzed due to trial termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline on the Functional Activities Questionnaire (FAQ)

End point title	Change from Baseline on the Functional Activities Questionnaire (FAQ)

End point description:

FAQ is a 10-item, caregiver-based questionnaire and was administered to the study partner who was asked to rate the participant's ability to perform a variety of activities ranging from Writing checks, Assembling tax records, shopping, playing games, food preparation, traveling, keeping appointments, Traveling out of neighborhood, keeping track of current events and understanding media. FAQ total score was calculated by adding the scores from each of the 10 items. Each activity is rated on a scale from 0 to 3 (Never did and would have difficulty now = 1; Never did [the activity] but could do now = 0; Normal = 0; Has difficulty but does by self = 1; Requires assistance = 2; Dependent = 3). The maximum FAQ total score is 30, with higher scores indicating greater impairment.

End point type	Secondary

End point timeframe:

Baseline, 24 Months

End point values	Solanezumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[10]	0[11]		
Units: NA				

Notes:

[10] - Zero participants were analyzed due to trial termination.

[11] - Zero participants were analyzed due to trial termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline on the Neuropsychiatric Inventory (NPI)

End point title	Change from Baseline on the Neuropsychiatric Inventory (NPI)

End point description:

The NPI is a tool for assessing psychopathology in participants with dementia and other neurologic disorders. Information is obtained from a caregiver familiar with the participant's behavior. The score ranges from 0 to 144, with higher scores indicating greater disease severity.

End point type	Secondary

End point timeframe:

Baseline, 24 Months

End point values	Solanezumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[12]	0[13]		
Units: NA				

Notes:

[12] - Zero participants were analyzed due to trial termination.

[13] - Zero participants were analyzed due to trial termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline on the Clinical Dementia Rating Scale Sum of Boxes (CDR-SB)

End point title	Change from Baseline on the Clinical Dementia Rating Scale Sum of Boxes (CDR-SB)

End point description:

CDR-SB is a semi-structured interview of participants and their caregivers. Participant's cognitive status is rated across 6 domains of functioning, including memory, orientation, judgment/problem solving, community affairs, home/hobbies, and personal care. Severity score assigned for each of 6 domains; total score (SB) ranges from 0 to 18. Higher scores indicate greater disease severity.

End point type	Secondary

End point timeframe:

Baseline, 24 Months

End point values	Solanezumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[14]	0[15]		
Units: NA				

Notes:

[14] - Zero participants were analyzed due to trial termination.

[15] - Zero participants were analyzed due to trial termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline on the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS)

End point title	Change from Baseline on the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS)

End point description:

RBANS is a brief neurocognitive battery with four alternate forms, measuring immediate and delayed memory, attention, language, and visuospatial/constructional skills.

End point type	Secondary

End point timeframe:

Baseline, 24 Months

End point values	Solanezumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[16]	0[17]		
Units: NA				

Notes:

[16] - Zero participants were analyzed due to trial termination.

[17] - Zero participants were analyzed due to trial termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline on the Free and Cued Selective Reminding Test (FCSRT)

End point title	Change from Baseline on the Free and Cued Selective Reminding Test (FCSRT)

End point description:

The FCSRT is a neuropsychological test of memory under conditions that control attention and cognitive processing in order to obtain an assessment of memory unconfounded by normal age-related changes in cognition.

End point type	Secondary

End point timeframe:

Baseline, 24 Months

End point values	Solanezumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[18]	0[19]		
Units: NA				

Notes:

[18] - Zero participants were analyzed due to trial termination.

[19] - Zero participants were analyzed due to trial termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline on the Resource Utilization in Dementia–Lite (RUD-Lite)

End point title	Change from Baseline on the Resource Utilization in Dementia–Lite (RUD-Lite)

End point description:

RUD-Lite assesses the healthcare resource utilization of participants and their caregivers to determine the level of formal and informal care attributable to Alzheimer's Disease (AD). Information on both caregivers (caregiving time, work status) and participants (accommodation and healthcare resource utilization) is collected from the baseline and follow-up interviews.

End point type	Secondary

End point timeframe:

Baseline, 24 Months

End point values	Solanezumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[20]	0[21]		
Units: NA				

Notes:

[20] - Zero participants were analyzed due to trial termination.

[21] - Zero participants were analyzed due to trial termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline on the EuroQol 5-Dimensional Health-Related Quality of Life Scale (EQ-5D)

End point title	Change from Baseline on the EuroQol 5-Dimensional Health-Related Quality of Life Scale (EQ-5D)

End point description:

EQ-5D (proxy version) measures mobility, self-care, usual activities, pain/discomfort, anxiety/depression; each has 3 severity levels (no, some, severe problems) coded to a 1-digit number (1-3). Digits are combined into 5-digit number describing health state. Visual analogue scale (VAS) assesses caregiver's impression of participant's overall health state; scores range: 0 to 100. Lower scores indicate greater disease severity.

End point type	Secondary

End point timeframe:

Baseline, 24 Months

End point values	Solanezumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[22]	0[23]		
Units: NA				

Notes:

[22] - Zero participants were analyzed due to trial termination.

[23] - Zero participants were analyzed due to trial termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline on the Quality of Life in Alzheimer’s Disease Scale (QoL-AD)

End point title	Change from Baseline on the Quality of Life in Alzheimer’s Disease Scale (QoL-AD)

End point description:

QoL for AD assess participant rates mood, relationships, memory, finances, physical condition, and

overall QoL assessment. Each of 13 items rated on a 4-point scale. Sum of items=total score (range: 13-52). Higher scores=greater QoL.

End point type	Secondary

End point timeframe:

Baseline, 24 Months

End point values	Solanezumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[24]	0[25]		
Units: NA				

Notes:

[24] - Zero participants were analyzed due to trial termination.

[25] - Zero participants were analyzed due to trial termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Concentration of Plasma Amyloid-β Peptide (Aβ) and Plasma Solanezumab

End point title	Change from Baseline in Concentration of Plasma Amyloid-β Peptide (Aβ) and Plasma Solanezumab

End point description:

Concentration of amino acid peptide known as Aβ 1-42 in plasma.

End point type	Secondary

End point timeframe:

Baseline, 24 Months

End point values	Solanezumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[26]	0[27]		
Units: NA				

Notes:

[26] - Zero participants were analyzed due to trial termination.

[27] - Zero participants were analyzed due to trial termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Volumetric Magnetic Resonance Imaging (vMRI)

End point title	Change from Baseline in Volumetric Magnetic Resonance Imaging (vMRI)

End point description:

MRI will be used to assess the effect of treatment on rate of whole brain volume.

End point type	Secondary

End point timeframe:

Baseline, 24 Months

End point values	Solanezumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[28]	0[29]		
Units: NA				

Notes:

[28] - Zero participants were analyzed due to trial termination.

[29] - Zero participants were analyzed due to trial termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Florbetapir Positron Emission Tomography (PET) Standardized Uptake Value Ratio (SUVr)

End point title	Change from Baseline in Florbetapir Positron Emission Tomography (PET) Standardized Uptake Value Ratio (SUVr)

End point description:

Florbetapir F18 PET used to assess the treatment effect in brain amyloid plaque deposition from baseline through 18 months as measured by florbetapir F18 PET Standardized Uptake Uptake Value ratio.

End point type	Secondary

End point timeframe:

Baseline, 24 Months

End point values	Solanezumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[30]	0[31]		
Units: NA				

Notes:

[30] - Zero participants were analyzed due to trial termination.

[31] - Zero participants were analyzed due to trial termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Concentration of Cerebrospinal Fluid (CSF) Aβ and CSF Tau Proteins

End point title	Change from Baseline in Concentration of Cerebrospinal Fluid (CSF) Aβ and CSF Tau Proteins

End point description:

Changes in CSF parameters, including total and free Aβ1-40 and Aβ1-42 species and total tau and P-tau181 peptides, will be assessed.

End point type	Secondary

End point timeframe:

Baseline, 24 Months

End point values	Solanezumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[32]	0[33]		
Units: NA				

Notes:

[32] - Zero participants were analyzed due to trial termination.

[33] - Zero participants were analyzed due to trial termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Neocortical Tau Deposits using 18F-AV-1451 PET

End point title	Change from Baseline in Neocortical Tau Deposits using 18F-AV-1451 PET

End point description:

Biomarker change will be analyzed to provide biomarker-based evidence that solanezumab affects the underlying disease pathology.

End point type	Secondary

End point timeframe:

Baseline, 24 Months

End point values	Solanezumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[34]	0[35]		
Units: NA				

Notes:

[34] - Zero participants were analyzed due to trial termination.

[35] - Zero participants were analyzed due to trial termination.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Entire Study	
Adverse event reporting additional description:	
H8A-MC-LZBE	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	20.0

Reporting groups	
Reporting group title	Solanezumab 400 mg
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Serious adverse events	Solanezumab 400 mg	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 13 (15.38%)	1 / 13 (7.69%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Cardiac disorders			
coronary artery disease			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
syncope			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
pneumonia			
alternative dictionary used: MedDRA 20.0			

subjects affected / exposed	0 / 13 (0.00%)	1 / 13 (7.69%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Solanezumab 400 mg	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 13 (53.85%)	1 / 13 (7.69%)	
Injury, poisoning and procedural complications			
fall			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 13 (0.00%)	
occurrences (all)	1	0	
skin abrasion			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 13 (0.00%)	
occurrences (all)	4	0	
Cardiac disorders			
coronary artery disease			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 13 (0.00%)	
occurrences (all)	2	0	
Surgical and medical procedures			
endodontic procedure			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 13 (0.00%)	
occurrences (all)	1	0	
General disorders and administration site conditions			
extravasation			
alternative dictionary used: MedDRA 20.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 13 (0.00%)	
occurrences (all)	2	0	
Gastrointestinal disorders			

constipation alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 13 (0.00%) 0	
Respiratory, thoracic and mediastinal disorders pulmonary hypertension alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 13 (0.00%) 0	
upper-airway cough syndrome alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 13 (7.69%) 1	
Psychiatric disorders insomnia alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 13 (0.00%) 0	
Musculoskeletal and connective tissue disorders Spinal osteoarthritis alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 13 (0.00%) 0	
Infections and infestations upper respiratory tract infection alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	2 / 13 (15.38%) 2	1 / 13 (7.69%) 1	
viral upper respiratory tract infection alternative dictionary used: MedDRA 20.0 subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 13 (0.00%) 0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The study was terminated due to insufficient scientific evidence that solanezumab would likely demonstrate a meaningful benefit to participants with prodromal AD as defined by the study protocol.

Notes: