Clinical trial results:
A Multicenter, Randomized, Addition to Baseline Treatment, Double-Blind, Placebo-Controlled, Phase III Study to Evaluate the Efficacy and Safety of Satralizumab (SA237) in Patients with Neuromyelitis Optica (NMO) and NMO Spectrum Disorder (NMOSD)

Summary

EudraCT number	2013-003752-21
Trial protocol	GB DE IT PL HU ES
Global end of trial date	

Results information

Result version number	v2
This version publication date	06 January 2023
First version publication date	27 September 2020
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	BN40898

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02028884
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Hoffmann-La Roche
Sponsor organisation address	Grenzacherstrasse 124, Basel, Switzerland, CH-4070
Public contact	F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, 41 616878333, global.trial_information@roche.com
Scientific contact	Medical Communications, Hoffmann-La Roche, 41 616878333, global.trial_information@roche.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-001625-PIP01-14
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	Interim
Date of interim/final analysis	06 June 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	06 June 2018
Global end of trial reached?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this study was to evaluate the efficacy of satralizumab, compared with placebo, in addition to baseline immunosuppressive treatment in participants with neuromyelitis optica (NMO) and NMO spectrum disorder (NMOSD).

Protection of trial subjects:

All study subjects were required to read and sign an Informed Consent Form.

Background therapy:

All patients received azathioprine or mycophenolate mofetil and/or corticosteroids as background therapy

Evidence for comparator: -

Actual start date of recruitment	20 February 2014
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	1 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Spain: 3
Country: Number of subjects enrolled	Germany: 4
Country: Number of subjects enrolled	France: 1
Country: Number of subjects enrolled	United Kingdom: 3
Country: Number of subjects enrolled	Hungary: 2
Country: Number of subjects enrolled	Italy: 9
Country: Number of subjects enrolled	Japan: 22
Country: Number of subjects enrolled	Poland: 23
Country: Number of subjects enrolled	Taiwan: 13
Country: Number of subjects enrolled	Ukraine: 3
Country: Number of subjects enrolled	United States: 2
Worldwide total number of subjects	85
EEA total number of subjects	42

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)	9
Adults (18-64 years)	72
From 65 to 84 years	4
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Participants took part in the double-blind (DB) period up to the primary clinical cut-off date (06 June 2018) and in the Open-label Extension Period until the final clinical cut-off date (23-Dec-2021). All ongoing patients have been offered to transition to the WN42349 study

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo + Baseline Treatment, then Satralizumab

Arm description:

Participants received matching placebo, subcutaneous (SC) at Weeks 0, 2 and 4, and every 4 weeks (Q4W) thereafter throughout the double-blind (DB) period up to protocol-defined relapse or treated relapse in addition to baseline treatment. Following the DB period all participants received satralizumab 120 mg SC injection (with or without baseline treatment) at Weeks 0, 2 and 4, and Q4W thereafter up to the clinical cut-off date (CCOD). At the CCOD, participants who had not experienced a relapse during the DB period were invited to initiate satralizumab 120 mg SC injection (with or without baseline treatment at Weeks 0, 2 and 4, and Q4W thereafter) after 4 weeks from their last study treatment dose in the DB period.

Arm type	Experimental
Investigational medicinal product name	Satralizumab
Investigational medicinal product code	
Other name	SA237 RG6168 RO5333787
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Satralizumab was administered subcutaneously (SC) at Weeks 0, 2, and 4, and thereafter once every 4 weeks (Q4W).

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo was administered subcutaneously (SC) at Weeks 0, 2, and 4, and thereafter once every 4 weeks (Q4W).

Arm title	Satralizumab + Baseline Treatment, then Satralizumab

Arm description:

Participants received satralizumab 120 mg SC injection at Weeks 0, 2 and 4, and Q4W thereafter throughout the DB period up to protocol-defined relapse or treated relapse in addition to baseline treatment. Following the DB period all participants received satralizumab 120 mg SC injection (with or without baseline treatment) at Weeks 0, 2 and 4, and Q4W thereafter up to the CCOD. At the CCOD, participants who had not experienced a relapse during the DB period were invited to continue satralizumab 120 mg SC injection (with or without baseline treatment at Weeks 0, 2 and 4, and Q4W

thereafter) after 4 weeks from their last study treatment dose in the DB period.

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo was administered subcutaneously (SC) at Weeks 0, 2, and 4, and thereafter once every 4 weeks (Q4W).

Investigational medicinal product name	Satralizumab
Investigational medicinal product code	
Other name	SA237 RG6168 RO5333787
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Satralizumab was administered subcutaneously (SC) at Weeks 0, 2, and 4, and thereafter once every 4 weeks (Q4W).

Arm title	SA237 - Enrolled in Open-Label

Arm description:

In the open-label extension period, the participant received an SC injection of satralizumab at Weeks 0,2, and 4, and Q4W thereafter, in addition to baseline treatment

Arm type	Experimental
Investigational medicinal product name	Satralizumab
Investigational medicinal product code	
Other name	SA237 RG6168 RO5333787
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Satralizumab was administered subcutaneously (SC) at Weeks 0, 2, and 4, and thereafter once every 4 weeks (Q4W).

Number of subjects in period 1	Placebo + Baseline Treatment, then Satralizumab	Satralizumab + Baseline Treatment, then Satralizumab	SA237 - Enrolled in Open-Label
Started	42	42	1
Completed	32	39	1
Not completed	10	3	0
Consent withdrawn by subject	2	-	-
Adverse event, non-fatal	5	3	-
Eligibility Violation	1	-	-
Non-Compliance With Study Drug	2	-	-

Period 2

Period 2 title	Open-label Extension Period
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo + Baseline Treatment, then Satralizumab

Arm description:

Participants received matching placebo, subcutaneous (SC) at Weeks 0, 2 and 4, and every 4 weeks (Q4W) thereafter throughout the double-blind (DB) period up to protocol-defined relapse or treated relapse in addition to baseline treatment. Following the DB period all participants received satralizumab 120 mg SC injection (with or without baseline treatment) at Weeks 0, 2 and 4, and Q4W thereafter up to the clinical cut-off date (CCOD). At the CCOD, participants who had not experienced a relapse during the DB period were invited to initiate satralizumab 120 mg SC injection (with or without baseline treatment at Weeks 0, 2 and 4, and Q4W thereafter) after 4 weeks from their last study treatment dose in the DB period.

Arm type	Experimental
Investigational medicinal product name	Satralizumab
Investigational medicinal product code	
Other name	SA237 RG6168 RO5333787
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Satralizumab was administered subcutaneously (SC) at Weeks 0, 2, and 4, and thereafter once every 4 weeks (Q4W).

Arm title	Satralizumab + Baseline Treatment, then Satralizumab

Arm description:

Participants received satralizumab 120 mg SC injection at Weeks 0, 2 and 4, and Q4W thereafter throughout the DB period up to protocol-defined relapse or treated relapse in addition to baseline treatment. Following the DB period all participants received satralizumab 120 mg SC injection (with or without baseline treatment) at Weeks 0, 2 and 4, and Q4W thereafter up to the CCOD. At the CCOD, participants who had not experienced a relapse during the DB period were invited to continue satralizumab 120 mg SC injection (with or without baseline treatment at Weeks 0, 2 and 4, and Q4W thereafter) after 4 weeks from their last study treatment dose in the DB period.

Arm type	Experimental
Investigational medicinal product name	Satralizumab
Investigational medicinal product code	
Other name	SA237 RG6168 RO5333787
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Satralizumab was administered subcutaneously (SC) at Weeks 0, 2, and 4, and thereafter once every 4 weeks (Q4W).

Arm title	SA237 - Enrolled in Open-Label

Arm description:

In the open-label extension period, the participant received an SC injection of satralizumab at Weeks 0,2, and 4, and Q4W thereafter, in addition to baseline treatment

Arm type	Experimental
Investigational medicinal product name	Satralizumab
Investigational medicinal product code	
Other name	SA237 RG6168 RO5333787
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Satralizumab was administered subcutaneously (SC) at Weeks 0, 2, and 4, and thereafter once every 4 weeks (Q4W).

Number of subjects in period 2	Placebo + Baseline Treatment, then Satralizumab	Satralizumab + Baseline Treatment, then Satralizumab	SA237 - Enrolled in Open-Label
Started	32	39	1
Completed	23	31	1
Not completed	9	8	0
Consent withdrawn by subject	-	6	-
Adverse event, non-fatal	3	1	-
Switched to another treatment option	3	-	-
Refused Treatment/Did Not Cooperate	-	1	-
Lack of efficacy	3	-	-

Baseline characteristics

Reporting groups

Reporting group title	Placebo + Baseline Treatment, then Satralizumab

Reporting group description:

Participants received matching placebo, subcutaneous (SC) at Weeks 0, 2 and 4, and every 4 weeks (Q4W) thereafter throughout the double-blind (DB) period up to protocol-defined relapse or treated relapse in addition to baseline treatment. Following the DB period all participants received satralizumab 120 mg SC injection (with or without baseline treatment) at Weeks 0, 2 and 4, and Q4W thereafter up to the clinical cut-off date (CCOD). At the CCOD, participants who had not experienced a relapse during the DB period were invited to initiate satralizumab 120 mg SC injection (with or without baseline treatment at Weeks 0, 2 and 4, and Q4W thereafter) after 4 weeks from their last study treatment dose in the DB period.

Reporting group title	Satralizumab + Baseline Treatment, then Satralizumab

Reporting group description:

Participants received satralizumab 120 mg SC injection at Weeks 0, 2 and 4, and Q4W thereafter throughout the DB period up to protocol-defined relapse or treated relapse in addition to baseline treatment. Following the DB period all participants received satralizumab 120 mg SC injection (with or without baseline treatment) at Weeks 0, 2 and 4, and Q4W thereafter up to the CCOD. At the CCOD, participants who had not experienced a relapse during the DB period were invited to continue satralizumab 120 mg SC injection (with or without baseline treatment at Weeks 0, 2 and 4, and Q4W thereafter) after 4 weeks from their last study treatment dose in the DB period.

Reporting group title	SA237 - Enrolled in Open-Label

Reporting group description:

In the open-label extension period, the participant received an SC injection of satralizumab at Weeks 0,2, and 4, and Q4W thereafter, in addition to baseline treatment

Reporting group values	Placebo + Baseline Treatment, then Satralizumab	Satralizumab + Baseline Treatment, then Satralizumab	SA237 - Enrolled in Open-Label
Number of subjects	42	42	1
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	3	5	1
Adults (18-64 years)	38	34	0
From 65-84 years	1	3	0
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	43.4	40.2	16.0
standard deviation	± 12.0	± 16.3	± 0
Sex: Female, Male Units:			
Male	2	4	0
Female	40	38	1

Race/Ethnicity, Customized Units: Subjects			
Not Hispanic or Latino	40	42	1
Not Stated	2	0	0
Race/Ethnicity, Customized Units: Subjects			
Asian	18	18	0
Black or African American	2	0	0
White	21	24	0
Other	1	0	1

Reporting group values	Total		
Number of subjects	85		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	9		
Adults (18-64 years)	72		
From 65-84 years	4		
85 years and over	0		
Age Continuous Units: Years			
arithmetic mean			
standard deviation	-		
Sex: Female, Male Units:			
Male	6		
Female	79		
Race/Ethnicity, Customized Units: Subjects			
Not Hispanic or Latino	83		
Not Stated	2		
Race/Ethnicity, Customized Units: Subjects			
Asian	36		
Black or African American	2		
White	45		
Other	2		

Subject analysis sets	
Subject analysis set title	Placebo + Baseline Treatment
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received matching placebo, subcutaneous (SC) at Weeks 0, 2 and 4, and every 4 weeks (Q4W) thereafter throughout the double-blind (DB) period up to protocol-defined relapse or treated

relapse in addition to baseline treatment. Following the DB period all participants received satralizumab 120 mg SC injection (with or without baseline treatment) at Weeks 0, 2 and 4, and Q4W thereafter up to the clinical cut-off date (CCOD). At the CCOD, participants who had not experienced a relapse during the DB period were invited to initiate satralizumab 120 mg SC injection (with or without baseline treatment at Weeks 0, 2 and 4, and Q4W thereafter) after 4 weeks from their last study treatment dose in the DB period.

Subject analysis set title	Satralizumab + Baseline Treatment
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received satralizumab 120 mg SC injection at Weeks 0, 2 and 4, and Q4W thereafter throughout the DB period up to protocol-defined relapse or treated relapse in addition to baseline treatment. Following the DB period all participants received satralizumab 120 mg SC injection (with or without baseline treatment) at Weeks 0, 2 and 4, and Q4W thereafter up to the CCOD. At the CCOD, participants who had not experienced a relapse during the DB period were invited to continue satralizumab 120 mg SC injection (with or without baseline treatment at Weeks 0, 2 and 4, and Q4W thereafter) after 4 weeks from their last study treatment dose in the DB period.

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Subject analysis set description:

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Subject analysis set type	Per protocol

Subject analysis set description:

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Subject analysis set type	Per protocol

Subject analysis set description:

Participants received satralizumab 120 mg SC injection at Weeks 0, 2 and 4, and Q4W thereafter throughout the DB period up to protocol-defined relapse or treated relapse in addition to baseline treatment. Following the DB period all participants received satralizumab 120 mg SC injection (with or without baseline treatment) at Weeks 0, 2 and 4, and Q4W thereafter up to the CCOD. At the CCOD, participants who had not experienced a relapse during the DB period were invited to continue satralizumab 120 mg SC injection (with or without baseline treatment at Weeks 0, 2 and 4, and Q4W thereafter) after 4 weeks from their last study treatment dose in the DB period.

Subject analysis set title	Placebo + Baseline Treatment
Subject analysis set type	Per protocol

Subject analysis set description:

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Subject analysis set title	Satralizumab + Baseline Treatment
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received satralizumab 120 mg SC injection at Weeks 0, 2 and 4, and Q4W thereafter

throughout the DB period up to protocol-defined relapse or treated relapse in addition to baseline treatment. Following the DB period all participants received satralizumab 120 mg SC injection (with or without baseline treatment) at Weeks 0, 2 and 4, and Q4W thereafter up to the CCOD. At the CCOD, participants who had not experienced a relapse during the DB period were invited to continue satralizumab 120 mg SC injection (with or without baseline treatment at Weeks 0, 2 and 4, and Q4W thereafter) after 4 weeks from their last study treatment dose in the DB period.

Subject analysis set title	Placebo + Baseline Treatment
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received matching placebo, subcutaneous (SC) at Weeks 0, 2 and 4, and every 4 weeks (Q4W) thereafter throughout the double-blind (DB) period up to protocol-defined relapse or treated relapse in addition to baseline treatment. Following the DB period all participants received satralizumab 120 mg SC injection (with or without baseline treatment) at Weeks 0, 2 and 4, and Q4W thereafter up to the clinical cut-off date (CCOD). At the CCOD, participants who had not experienced a relapse during the DB period were invited to initiate satralizumab 120 mg SC injection (with or without baseline treatment at Weeks 0, 2 and 4, and Q4W thereafter) after 4 weeks from their last study treatment dose in the DB period.

Subject analysis set title	Satralizumab + Baseline Treatment
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received satralizumab 120 mg SC injection at Weeks 0, 2 and 4, and Q4W thereafter throughout the DB period up to protocol-defined relapse or treated relapse in addition to baseline treatment. Following the DB period all participants received satralizumab 120 mg SC injection (with or without baseline treatment) at Weeks 0, 2 and 4, and Q4W thereafter up to the CCOD. At the CCOD, participants who had not experienced a relapse during the DB period were invited to continue satralizumab 120 mg SC injection (with or without baseline treatment at Weeks 0, 2 and 4, and Q4W thereafter) after 4 weeks from their last study treatment dose in the DB period.

Subject analysis set title	Satralizumab + Baseline Treatment
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received satralizumab 120 mg SC injection at Weeks 0, 2 and 4, and Q4W thereafter throughout the DB period up to protocol-defined relapse or treated relapse in addition to baseline treatment. Following the DB period all participants received satralizumab 120 mg SC injection (with or without baseline treatment) at Weeks 0, 2 and 4, and Q4W thereafter up to the CCOD. At the CCOD, participants who had not experienced a relapse during the DB period were invited to continue satralizumab 120 mg SC injection (with or without baseline treatment at Weeks 0, 2 and 4, and Q4W thereafter) after 4 weeks from their last study treatment dose in the DB period.

Reporting group values	Placebo + Baseline Treatment	Satralizumab + Baseline Treatment	Satralizumab + Baseline Treatment
Number of subjects	42	42	41
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous Units: Years			
arithmetic mean	43.4	40.2	
standard deviation	± 12.00	± 16.3	±

Sex: Female, Male Units:			
Male	2	4	
Female	40	38	
Race/Ethnicity, Customized Units: Subjects			
Not Hispanic or Latino	40	42	
Not Stated	2	0	
Race/Ethnicity, Customized Units: Subjects			
Asian	18	18	
Black or African American	2	0	
White	21	24	
Other	1	0	

Reporting group values	Placebo + Baseline Treatment	Satralizumab + Baseline Treatment	Placebo + Baseline Treatment
Number of subjects	34	37	16
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous Units: Years arithmetic mean standard deviation	±	±	±
Sex: Female, Male Units:			
Male Female			
Race/Ethnicity, Customized Units: Subjects			
Not Hispanic or Latino Not Stated			
Race/Ethnicity, Customized Units: Subjects			
Asian Black or African American White Other			

Reporting group values	Satralizumab + Baseline Treatment	Placebo + Baseline Treatment	Satralizumab + Baseline Treatment
Number of subjects	13	41	40

Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous Units: Years arithmetic mean standard deviation	±	±	±
Sex: Female, Male Units:			
Male Female			
Race/Ethnicity, Customized Units: Subjects			
Not Hispanic or Latino Not Stated			
Race/Ethnicity, Customized Units: Subjects			
Asian Black or African American White Other			

Reporting group values	Satralizumab + Baseline Treatment		
Number of subjects	75		
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous Units: Years arithmetic mean standard deviation	±		

Sex: Female, Male Units:			
Male Female			
Race/Ethnicity, Customized Units: Subjects			
Not Hispanic or Latino Not Stated			
Race/Ethnicity, Customized Units: Subjects			
Asian Black or African American White Other			

End points reporting groups

Reporting group title	Placebo + Baseline Treatment, then Satralizumab

Reporting group description:

Participants received matching placebo, subcutaneous (SC) at Weeks 0, 2 and 4, and every 4 weeks (Q4W) thereafter throughout the double-blind (DB) period up to protocol-defined relapse or treated relapse in addition to baseline treatment. Following the DB period all participants received satralizumab 120 mg SC injection (with or without baseline treatment) at Weeks 0, 2 and 4, and Q4W thereafter up to the clinical cut-off date (CCOD). At the CCOD, participants who had not experienced a relapse during the DB period were invited to initiate satralizumab 120 mg SC injection (with or without baseline treatment at Weeks 0, 2 and 4, and Q4W thereafter) after 4 weeks from their last study treatment dose in the DB period.

Reporting group title	Satralizumab + Baseline Treatment, then Satralizumab

Reporting group description:

Participants received satralizumab 120 mg SC injection at Weeks 0, 2 and 4, and Q4W thereafter throughout the DB period up to protocol-defined relapse or treated relapse in addition to baseline treatment. Following the DB period all participants received satralizumab 120 mg SC injection (with or without baseline treatment) at Weeks 0, 2 and 4, and Q4W thereafter up to the CCOD. At the CCOD, participants who had not experienced a relapse during the DB period were invited to continue satralizumab 120 mg SC injection (with or without baseline treatment at Weeks 0, 2 and 4, and Q4W thereafter) after 4 weeks from their last study treatment dose in the DB period.

Reporting group title	SA237 - Enrolled in Open-Label

Reporting group description:

In the open-label extension period, the participant received an SC injection of satralizumab at Weeks 0,2, and 4, and Q4W thereafter, in addition to baseline treatment

Reporting group title	Placebo + Baseline Treatment, then Satralizumab

Reporting group description:

Participants received matching placebo, subcutaneous (SC) at Weeks 0, 2 and 4, and every 4 weeks (Q4W) thereafter throughout the double-blind (DB) period up to protocol-defined relapse or treated relapse in addition to baseline treatment. Following the DB period all participants received satralizumab 120 mg SC injection (with or without baseline treatment) at Weeks 0, 2 and 4, and Q4W thereafter up to the clinical cut-off date (CCOD). At the CCOD, participants who had not experienced a relapse during the DB period were invited to initiate satralizumab 120 mg SC injection (with or without baseline treatment at Weeks 0, 2 and 4, and Q4W thereafter) after 4 weeks from their last study treatment dose in the DB period.

Reporting group title	Satralizumab + Baseline Treatment, then Satralizumab

Reporting group description:

Participants received satralizumab 120 mg SC injection at Weeks 0, 2 and 4, and Q4W thereafter throughout the DB period up to protocol-defined relapse or treated relapse in addition to baseline treatment. Following the DB period all participants received satralizumab 120 mg SC injection (with or without baseline treatment) at Weeks 0, 2 and 4, and Q4W thereafter up to the CCOD. At the CCOD, participants who had not experienced a relapse during the DB period were invited to continue satralizumab 120 mg SC injection (with or without baseline treatment at Weeks 0, 2 and 4, and Q4W thereafter) after 4 weeks from their last study treatment dose in the DB period.

Reporting group title	SA237 - Enrolled in Open-Label

Reporting group description:

In the open-label extension period, the participant received an SC injection of satralizumab at Weeks 0,2, and 4, and Q4W thereafter, in addition to baseline treatment

Subject analysis set title	Placebo + Baseline Treatment
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received matching placebo, subcutaneous (SC) at Weeks 0, 2 and 4, and every 4 weeks (Q4W) thereafter throughout the double-blind (DB) period up to protocol-defined relapse or treated relapse in addition to baseline treatment. Following the DB period all participants received satralizumab 120 mg SC injection (with or without baseline treatment) at Weeks 0, 2 and 4, and Q4W thereafter up to the clinical cut-off date (CCOD). At the CCOD, participants who had not experienced a relapse during the DB period were invited to initiate satralizumab 120 mg SC injection (with or without baseline treatment at Weeks 0, 2 and 4, and Q4W thereafter) after 4 weeks from their last study treatment dose in the DB period.

Subject analysis set title	Satralizumab + Baseline Treatment
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received satralizumab 120 mg SC injection at Weeks 0, 2 and 4, and Q4W thereafter throughout the DB period up to protocol-defined relapse or treated relapse in addition to baseline treatment. Following the DB period all participants received satralizumab 120 mg SC injection (with or without baseline treatment) at Weeks 0, 2 and 4, and Q4W thereafter up to the CCOD. At the CCOD, participants who had not experienced a relapse during the DB period were invited to continue satralizumab 120 mg SC injection (with or without baseline treatment at Weeks 0, 2 and 4, and Q4W thereafter) after 4 weeks from their last study treatment dose in the DB period.

Subject analysis set title	Satralizumab + Baseline Treatment
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received satralizumab 120 mg SC injection at Weeks 0, 2 and 4, and Q4W thereafter throughout the DB period up to protocol-defined relapse or treated relapse in addition to baseline treatment. Following the DB period all participants received satralizumab 120 mg SC injection (with or without baseline treatment) at Weeks 0, 2 and 4, and Q4W thereafter up to the CCOD. At the CCOD, participants who had not experienced a relapse during the DB period were invited to continue satralizumab 120 mg SC injection (with or without baseline treatment at Weeks 0, 2 and 4, and Q4W thereafter) after 4 weeks from their last study treatment dose in the DB period.

Subject analysis set title	Placebo + Baseline Treatment
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received matching placebo, subcutaneous (SC) at Weeks 0, 2 and 4, and every 4 weeks (Q4W) thereafter throughout the double-blind (DB) period up to protocol-defined relapse or treated relapse in addition to baseline treatment. Following the DB period all participants received satralizumab 120 mg SC injection (with or without baseline treatment) at Weeks 0, 2 and 4, and Q4W thereafter up to the clinical cut-off date (CCOD). At the CCOD, participants who had not experienced a relapse during the DB period were invited to initiate satralizumab 120 mg SC injection (with or without baseline treatment at Weeks 0, 2 and 4, and Q4W thereafter) after 4 weeks from their last study treatment dose in the DB period.

Subject analysis set title	Satralizumab + Baseline Treatment
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received satralizumab 120 mg SC injection at Weeks 0, 2 and 4, and Q4W thereafter throughout the DB period up to protocol-defined relapse or treated relapse in addition to baseline treatment. Following the DB period all participants received satralizumab 120 mg SC injection (with or without baseline treatment) at Weeks 0, 2 and 4, and Q4W thereafter up to the CCOD. At the CCOD, participants who had not experienced a relapse during the DB period were invited to continue satralizumab 120 mg SC injection (with or without baseline treatment at Weeks 0, 2 and 4, and Q4W thereafter) after 4 weeks from their last study treatment dose in the DB period.

Subject analysis set title	Placebo + Baseline Treatment
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received matching placebo, subcutaneous (SC) at Weeks 0, 2 and 4, and every 4 weeks (Q4W) thereafter throughout the double-blind (DB) period up to protocol-defined relapse or treated relapse in addition to baseline treatment. Following the DB period all participants received satralizumab 120 mg SC injection (with or without baseline treatment) at Weeks 0, 2 and 4, and Q4W thereafter up to the clinical cut-off date (CCOD). At the CCOD, participants who had not experienced a relapse during the DB period were invited to initiate satralizumab 120 mg SC injection (with or without baseline treatment at Weeks 0, 2 and 4, and Q4W thereafter) after 4 weeks from their last study treatment dose in the DB period.

Subject analysis set title	Satralizumab + Baseline Treatment
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received satralizumab 120 mg SC injection at Weeks 0, 2 and 4, and Q4W thereafter throughout the DB period up to protocol-defined relapse or treated relapse in addition to baseline treatment. Following the DB period all participants received satralizumab 120 mg SC injection (with or without baseline treatment) at Weeks 0, 2 and 4, and Q4W thereafter up to the CCOD. At the CCOD, participants who had not experienced a relapse during the DB period were invited to continue satralizumab 120 mg SC injection (with or without baseline treatment at Weeks 0, 2 and 4, and Q4W thereafter) after 4 weeks from their last study treatment dose in the DB period.

Subject analysis set title	Placebo + Baseline Treatment
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received matching placebo, subcutaneous (SC) at Weeks 0, 2 and 4, and every 4 weeks (Q4W) thereafter throughout the double-blind (DB) period up to protocol-defined relapse or treated relapse in addition to baseline treatment. Following the DB period all participants received satralizumab 120 mg SC injection (with or without baseline treatment) at Weeks 0, 2 and 4, and Q4W thereafter up to the clinical cut-off date (CCOD). At the CCOD, participants who had not experienced a relapse during the DB period were invited to initiate satralizumab 120 mg SC injection (with or without baseline treatment at Weeks 0, 2 and 4, and Q4W thereafter) after 4 weeks from their last study treatment dose in the DB period.

Subject analysis set title	Satralizumab + Baseline Treatment
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received satralizumab 120 mg SC injection at Weeks 0, 2 and 4, and Q4W thereafter throughout the DB period up to protocol-defined relapse or treated relapse in addition to baseline treatment. Following the DB period all participants received satralizumab 120 mg SC injection (with or without baseline treatment) at Weeks 0, 2 and 4, and Q4W thereafter up to the CCOD. At the CCOD, participants who had not experienced a relapse during the DB period were invited to continue satralizumab 120 mg SC injection (with or without baseline treatment at Weeks 0, 2 and 4, and Q4W thereafter) after 4 weeks from their last study treatment dose in the DB period.

Subject analysis set title	Satralizumab + Baseline Treatment
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received satralizumab 120 mg SC injection at Weeks 0, 2 and 4, and Q4W thereafter throughout the DB period up to protocol-defined relapse or treated relapse in addition to baseline treatment. Following the DB period all participants received satralizumab 120 mg SC injection (with or without baseline treatment) at Weeks 0, 2 and 4, and Q4W thereafter up to the CCOD. At the CCOD, participants who had not experienced a relapse during the DB period were invited to continue satralizumab 120 mg SC injection (with or without baseline treatment at Weeks 0, 2 and 4, and Q4W thereafter) after 4 weeks from their last study treatment dose in the DB period.

Primary: Time to First Protocol-Defined Relapse (TFR) in the Double-Blind Period

End point title	Time to First Protocol-Defined Relapse (TFR) in the Double-Blind Period

End point description:

TFR was defined as time from randomization to first occurrence of relapse in the DB period. Protocol-defined relapse was occurrence of new or worsening neurological symptoms attributable to neurological neuromyelitis optica (NMO) or neuromyelitis optica spectrum disorder (NMOSD) as adjudicated by an independent clinical endpoint committee (CEC). Symptoms had to persist for >24 hours and not be attributable to confounding clinical factors (e.g., fever, infection, injury, change in mood, adverse reactions to medications). New or worsening neurological symptoms that occurred < 31 days following onset of a protocol-defined relapse were considered part of same relapse (i.e., if 2 relapses had onset days that were 30 days of one another, they were counted only as 1 relapse), and onset date used in analysis was the date of first relapse.

End point type	Primary

End point timeframe:

Up to Week 224

End point values	Placebo + Baseline Treatment	Satralizumab + Baseline Treatment		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	41		
Units: weeks				
median (confidence interval 95%)	120.6 (37.0 to 9999)	0000 (0000 to 9999)		

Statistical analyses

Statistical analysis title	Stratified analysis
Statistical analysis description:	
Stratified by Baseline annualized relapse rate (ARR: 1, > 1) and geographic region (Asia, EU/Other).	
Comparison groups	Placebo + Baseline Treatment v Satralizumab + Baseline Treatment
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0184
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.16
upper limit	0.88

Secondary: Change from Baseline at Week 24 in the Visual Analogue Scale (VAS) Score for Pain During the DB Period

End point title	Change from Baseline at Week 24 in the Visual Analogue Scale (VAS) Score for Pain During the DB Period
End point description:	
The VAS is a subjective measure of pain consisting of a 100 mm line with two endpoints representing 0 = "no pain" and 100 = "pain as bad as it could be". Participants rated their pain by placing a mark on the line corresponding to their current level of pain. The distance along the line from the "no pain" marker was measured with a ruler giving a pain score out of 100. A higher score indicated more pain and lower scores reflected a better health state. A negative change from baseline indicates an improvement. ANCOVA was used for analysis to report the adjusted mean and standard error (SE).	
End point type	Secondary
End point timeframe:	
Baseline, Week 24	

End point values	Placebo + Baseline Treatment	Satralizumab + Baseline Treatment		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	41		
Units: score on scale				
arithmetic mean (standard error)				

Baseline	34.619 (± 4.026)	27.561 (± 4.399)		
Change from Baseline at Week 24	-3.505 (± 2.357)	2.871 (± 2.391)		

Statistical analyses

Statistical analysis title	Statistical analysis
Comparison groups	Placebo + Baseline Treatment v Satralizumab + Baseline Treatment
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0602
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	6.376
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.28
upper limit	13.033
Variability estimate	Standard error of the mean
Dispersion value	3.344

Secondary: Change from Baseline at Week 24 in the Functional Assessment of Chronic Illness Therapy (FACIT) Fatigue Score During the DB Period

End point title	Change from Baseline at Week 24 in the Functional Assessment of Chronic Illness Therapy (FACIT) Fatigue Score During the DB Period

End point description:

The FACIT Fatigue scale is a 13-item questionnaire that assesses self-reported fatigue and its impact upon daily activities and function over the past 7 days. As each of the 13 items of the scale ranges from 0-4, the range of possible scores was computed using FACIT scoring algorithm as 0-52, where 0 is the worst possible score and 52 the best which indicated less fatigue. A positive change from baseline indicates an improvement. ANCOVA was used for analysis to report the adjusted mean and SE.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Placebo + Baseline Treatment	Satralizumab + Baseline Treatment		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	41		
Units: score on scale				
arithmetic mean (standard error)				

Baseline	33.857 (± 1.746)	34.732 (± 1.646)		
Change from Baseline at Week 24	2.234 (± 0.943)	0.145 (± 0.963)		

Statistical analyses

Statistical analysis title	Statistical analysis
Comparison groups	Placebo + Baseline Treatment v Satralizumab + Baseline Treatment
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1224
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-2.089
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.752
upper limit	0.574
Variability estimate	Standard error of the mean
Dispersion value	1.338

Secondary: Relapse-Free Rate During the DB Period

End point title	Relapse-Free Rate During the DB Period

End point description:

Protocol-defined relapse was occurrence of new or worsening neurological symptoms attributable to neurological neuromyelitis optica (NMO) or neuromyelitis optica spectrum disorder (NMOSD). Symptoms had to persist for >24 hours and not be attributable to confounding clinical factors (e.g., fever, infection, injury, change in mood, adverse reactions to medications). New or worsening neurological symptoms that occurred < 31 days following onset of a protocol-defined relapse were considered part of same relapse (i.e., if 2 relapses had onsets within 30 days of one another, they were counted as 1), and onset date used in analysis was the date of first relapse.

End point type	Secondary

End point timeframe:

Up to Week 216

End point values	Placebo + Baseline Treatment	Satralizumab + Baseline Treatment		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	34	37		
Units: percentage of participants				
number (not applicable)				
Week 12	89.86	94.99		

Week 24	84.41	88.86		
Week 36	69.49	88.86		
Week 48	66.02	88.86		
Week 72	58.68	81.46		
Week 96	58.68	77.58		
Week 120	54.17	73.70		
Week 144	49.24	73.70		
Week 168	43.77	73.70		
Week 192	0000	73.70		
Week 216	0000	73.70		

Statistical analyses

No statistical analyses for this end point

Secondary: Annualized Relapse Rate (ARR) During the DB Period

End point title	Annualized Relapse Rate (ARR) During the DB Period

End point description:

The ARR is calculated as the total number of participants with relapses experienced divided by the patient-years at risk. Protocol-defined relapse was occurrence of new or worsening neurological symptoms attributable to neurological NMO or NMOSD. Symptoms had to persist for >24 hours and not be attributable to confounding clinical factors (e.g., fever, infection, injury, change in mood, adverse reactions to medications). New or worsening neurological symptoms that occurred < 31 days following onset of a protocol-defined relapse were considered part of same relapse (2 relapses with onset days in 30 days of one another was counted as 1 relapse), onset date used in analysis was the date of first relapse.

End point type	Secondary

End point timeframe:

Up to Week 216

End point values	Placebo + Baseline Treatment	Satralizumab + Baseline Treatment		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	41		
Units: patients w relapse/patient-years at risk				
number (confidence interval 95%)	0.32 (0.19 to 0.51)	0.11 (0.05 to 0.21)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Modified Rankin Scale (mRS) Scores at 24 Week Intervals During the DB Period

End point title	Change from Baseline in Modified Rankin Scale (mRS) Scores

	at 24 Week Intervals During the DB Period

End point description:

The mRS is a 7-point disability scale that assesses the degree of disability in participants with neurological impairment. Possible scores range from 0 (no symptoms at all) up to 6 (death). Higher scores reflect increased disability. A negative change from baseline indicates an improvement.

End point type	Secondary

End point timeframe:

Baseline up to Week 216

End point values	Placebo + Baseline Treatment	Satralizumab + Baseline Treatment		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	41		
Units: score on scale				
arithmetic mean (standard deviation)				
Baseline	1.55 (± 0.97)	1.90 (± 1.14)		
Change from Baseline at Week 24	-0.03 (± 0.42)	-0.03 (± 0.50)		
Change from Baseline at Week 48	-0.18 (± 0.53)	-0.13 (± 0.45)		
Change from Baseline at Week 72	0.07 (± 0.70)	0.00 (± 0.52)		
Change from Baseline at Week 96	0.13 (± 0.62)	-0.19 (± 0.51)		
Change from Baseline at Week 120	-0.10 (± 0.74)	-0.05 (± 0.51)		
Change from Baseline at Week 144	-0.11 (± 0.93)	-0.20 (± 0.41)		
Change from Baseline at Week 168	-0.67 (± 0.58)	-0.11 (± 0.33)		
Change from Baseline at Week 192	0000 (± 0000)	-0.50 (± 0.71)		
Change from Baseline at Week 216	0000 (± 0000)	0.00 (± 0000)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Zarit Burden Interview (ZBI) Scores at 24 Week Intervals During the DB Period

End point title	Change from Baseline in Zarit Burden Interview (ZBI) Scores at 24 Week Intervals During the DB Period

End point description:

The ZBI is the measurement to assess caregiver burden. The 22 items ask for the strain caregivers perceive. Responses range from 0 (never) to 4 (nearly always). The overall ZBI score ranges from 0 to 88. The higher the total score, the heavier the perceived burden. A negative change from baseline indicates an improvement.

End point type	Secondary

End point timeframe:

Baseline up to Week 168

End point values	Placebo + Baseline Treatment	Satralizumab + Baseline Treatment		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	16	13		
Units: score on scale				
arithmetic mean (standard deviation)				
Baseline	19.31 (± 9.31)	18.92 (± 12.82)		
Change from Baseline at Week 24	-3.44 (± 5.59)	-3.57 (± 7.11)		
Change from Baseline at Week 48	1.17 (± 8.26)	1.13 (± 13.45)		
Change from Baseline at Week 72	2.20 (± 19.64)	-0.71 (± 11.60)		
Change from Baseline at Week 96	3.00 (± 14.98)	4.17 (± 13.33)		
Change from Baseline at Week 120	0.00 (± 3.61)	3.40 (± 9.29)		
Change from Baseline at Week 144	-3.50 (± 12.02)	-3.50 (± 11.33)		
Change from Baseline at Week 168	2.50 (± 13.44)	11.00 (± 0000)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Expanded Disability Status Scale (EDSS) Scores at 24 Week Intervals During the DB Period

End point title	Change from Baseline in Expanded Disability Status Scale (EDSS) Scores at 24 Week Intervals During the DB Period

End point description:

The EDSS is an ordinal scale with values from 0 points (normal neurological examination) to 10 points (death) increasing in half-point increments once an EDSS of 1.0 has been reached. Higher scores represent increased disability. A negative change from baseline indicates an improvement.

End point type	Secondary

End point timeframe:

Baseline up to Week 216

End point values	Placebo + Baseline Treatment	Satralizumab + Baseline Treatment		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	41	41		
Units: score on scale				
arithmetic mean (standard deviation)				
Baseline	3.63 (± 1.32)	3.83 (± 1.57)		
Change from Baseline at Week 24	-0.21 (± 0.68)	-0.14 (± 0.82)		
Change from Baseline at Week 48	-0.19 (± 0.77)	-0.19 (± 0.67)		
Change from Baseline at Week 72	-0.27 (± 0.68)	-0.29 (± 0.73)		
Change from Baseline at Week 96	-0.19 (± 0.81)	-0.19 (± 0.75)		
Change from Baseline at Week 120	-0.30 (± 0.79)	0.03 (± 0.57)		
Change from Baseline at Week 144	-0.33 (± 0.83)	-0.07 (± 0.62)		
Change from Baseline at Week 168	-0.17 (± 0.76)	-0.06 (± 0.58)		

Change from Baseline at Week 192	0000 (± 0000)	0.00 (± 0.71)		
Change from Baseline at Week 216	0000 (± 0000)	-0.50 (± 0000)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Visual Acuity (Snellen Chart) at 24 Week Intervals During the DB Period

End point title	Change from Baseline in Visual Acuity (Snellen Chart) at 24 Week Intervals During the DB Period

End point description:

Visual acuity was measured using Snellen 20-foot wall chart and then converted to logMAR visual acuity scoring. Lower values indicate better visual acuity. Data are reported for right eye (OD) and left eye (OS). A negative change from baseline indicates an improvement.

End point type	Secondary

End point timeframe:

Baseline up to Week 216

End point values	Placebo + Baseline Treatment	Satralizumab + Baseline Treatment		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	41		
Units: LogMAR units				
arithmetic mean (standard deviation)				
Baseline: OD	0.490 (± 0.928)	0.303 (± 0.593)		
Baseline: OS	0.526 (± 0.911)	0.597 (± 1.016)		
Change from Baseline at Week 24: OD	-0.064 (± 0.197)	0.042 (± 0.236)		
Change from Baseline at Week 24: OS	-0.012 (± 0.107)	0.059 (± 0.319)		
Change from Baseline at Week 48: OD	-0.019 (± 0.086)	0.008 (± 0.093)		
Change from Baseline at Week 48: OS	0.026 (± 0.096)	0.013 (± 0.061)		
Change from Baseline at Week 72: OD	-0.001 (± 0.110)	-0.034 (± 0.111)		
Change from Baseline at Week 72: OS	-0.001 (± 0.121)	-0.019 (± 0.077)		
Change from Baseline at Week 96: OD	0.018 (± 0.174)	-0.013 (± 0.095)		
Change from Baseline at Week 96: OS	-0.078 (± 0.185)	-0.010 (± 0.073)		
Change from Baseline at Week 120: OD	0.030 (± 0.150)	0.011 (± 0.103)		
Change from Baseline at Week 120: OS	-0.024 (± 0.150)	0.014 (± 0.257)		

Change from Baseline at Week 144: OD	0.058 (± 0.231)	-0.016 (± 0.120)		
Change from Baseline at Week 144: OS	-0.016 (± 0.165)	-0.028 (± 0.111)		
Change from Baseline at Week 168: OD	0.113 (± 0.306)	0.027 (± 0.199)		
Change from Baseline at Week 168: OS	0.100 (± 0.173)	-0.024 (± 0.113)		
Change from Baseline at Week 192: OD	0000 (± 0000)	0.150 (± 0.099)		
Change from Baseline at Week 192: OS	0000 (± 0000)	0.000 (± 0.000)		
Change from Baseline at Week 216: OD	0000 (± 0000)	0.120 (± 0000)		
Change from Baseline at Week 216: OS	0000 (± 0000)	0.000 (± 0000)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Short Form Generic Health Survey (SF-36) Mental Component Summary Scores at 24 Week Intervals During the DB Period

End point title	Change from Baseline in Short Form Generic Health Survey (SF-36) Mental Component Summary Scores at 24 Week Intervals During the DB Period

End point description:

The SF-36v2 is a multi-purpose, short form health survey with 36 questions. It has 8 domains (vitality, physical functioning, bodily pain, general health, role-physical, role emotional, social role functioning and mental health) of functional health and well-being scores as well as psychometrically based physical and mental health summary measures and a preference-based health utility index. The component scores were transformed to a 0-100 scale, where higher score indicates better quality of life. A positive change from baseline indicates an improvement.

End point type	Secondary

End point timeframe:

Baseline up to Week 216

End point values	Placebo + Baseline Treatment	Satralizumab + Baseline Treatment		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	41		
Units: score on scale				
arithmetic mean (standard deviation)				
Baseline	44.77 (± 11.08)	44.56 (± 9.75)		
Change from Baseline at Week 24	2.53 (± 7.58)	0.57 (± 8.99)		
Change from Baseline at Week 48	2.78 (± 7.51)	-0.61 (± 10.97)		
Change from Baseline at Week 72	3.47 (± 7.13)	2.78 (± 8.13)		
Change from Baseline at Week 96	5.16 (± 10.52)	1.06 (± 7.63)		
Change from Baseline at Week 120	3.63 (± 8.62)	0.71 (± 7.23)		
Change from Baseline at Week 144	2.83 (± 8.79)	3.82 (± 7.15)		
Change from Baseline at Week 168	2.79 (± 6.85)	3.60 (± 9.50)		

Change from Baseline at Week 192	0000 (± 0000)	11.60 (± 7.32)		
Change from Baseline at Week 216	0000 (± 0000)	14.05 (± 0000)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in SF-36 Physical Component Summary Scores at 24 Week Intervals During the DB Period

End point title	Change from Baseline in SF-36 Physical Component Summary Scores at 24 Week Intervals During the DB Period

End point description:

The SF-36v2 is a multi-purpose, short form health survey with 36 questions. It has 8 domains (vitality, physical functioning, bodily pain, general health, role-physical, role emotional, social role functioning and mental health) of functional health and well-being scores as well as psychometrically based physical and mental health summary measures and a preference-based health utility index. The component scores were transformed to a 0-100 scale, where higher score indicates better quality of life. A positive change from baseline indicates an improvement.

End point type	Secondary

End point timeframe:

Baseline up to Week 216

End point values	Placebo + Baseline Treatment	Satralizumab + Baseline Treatment		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	41		
Units: score on scale				
arithmetic mean (standard deviation)				
Baseline	41.54 (± 9.11)	43.60 (± 10.47)		
Change from Baseline at Week 24	2.79 (± 5.61)	1.30 (± 6.01)		
Change from Baseline at Week 48	0.18 (± 5.33)	1.22 (± 5.77)		
Change from Baseline at Week 72	1.97 (± 6.23)	1.16 (± 4.79)		
Change from Baseline at Week 96	-1.15 (± 7.52)	1.88 (± 5.72)		
Change from Baseline at Week 120	-0.13 (± 7.10)	2.34 (± 6.60)		
Change from Baseline at Week 144	1.78 (± 5.50)	3.05 (± 4.23)		
Change from Baseline at Week 168	0.22 (± 9.23)	0.76 (± 5.98)		
Change from Baseline at Week 192	0000 (± 0000)	0.23 (± 0.55)		
Change from Baseline at Week 216	0000 (± 0000)	-1.63 (± 0000)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in SF-36 Bodily Pain Domain Scores at 24 Week Intervals During the DB Period

End point title	Change from Baseline in SF-36 Bodily Pain Domain Scores at 24 Week Intervals During the DB Period

End point description:

The SF-36v2 is a multi-purpose, short form health survey with 36 questions. It has 8 domains (vitality, physical functioning, bodily pain, general health, role-physical, role emotional, social role functioning and mental health) of functional health and well-being scores as well as psychometrically based physical and mental health component summary measures and a preference-based health utility index. The domain scores were transformed to a 0-100 scale, where higher scores indicate better quality of life. A positive change from baseline indicates an improvement.

End point type	Secondary

End point timeframe:

Baseline up to Week 216

End point values	Placebo + Baseline Treatment	Satralizumab + Baseline Treatment		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	41		
Units: score on scale				
arithmetic mean (standard deviation)				
Baseline	43.91 (± 10.22)	45.94 (± 11.56)		
Change from Baseline at Week 24	2.71 (± 7.06)	0.03 (± 11.06)		
Change from Baseline at Week 48	0.81 (± 5.60)	0.12 (± 6.99)		
Change from Baseline at Week 72	3.55 (± 8.20)	2.30 (± 6.99)		
Change from Baseline at Week 96	1.31 (± 7.13)	1.15 (± 8.86)		
Change from Baseline at Week 120	2.22 (± 9.96)	-1.45 (± 9.13)		
Change from Baseline at Week 144	3.58 (± 8.53)	3.14 (± 8.18)		
Change from Baseline at Week 168	1.61 (± 10.58)	3.05 (± 9.00)		
Change from Baseline at Week 192	0000 (± 0000)	8.07 (± 0.57)		
Change from Baseline at Week 216	0000 (± 0000)	3.63 (± 0000)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in SF-36 General Health Domain Scores at 24 Week Intervals During the DB Period

End point title	Change from Baseline in SF-36 General Health Domain Scores at 24 Week Intervals During the DB Period

End point description:

The SF-36v2 is a multi-purpose, short form health survey with 36 questions. It has 8 domains (vitality, physical functioning, bodily pain, general health, role-physical, role emotional, social role functioning and mental health) of functional health and well-being scores as well as psychometrically based physical and mental health component summary measures and a preference-based health utility index. The domain scores were transformed to a 0-100 scale, where higher scores indicate better quality of life. A positive change from baseline indicates an improvement.

End point type	Secondary

End point timeframe:

Baseline up to Week 216

End point values	Placebo + Baseline Treatment	Satralizumab + Baseline Treatment		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	41		
Units: score on scale				
arithmetic mean (standard deviation)				
Baseline	39.65 (± 7.90)	41.23 (± 9.29)		
Change from Baseline at Week 24	1.84 (± 5.68)	-0.60 (± 7.26)		
Change from Baseline at Week 48	-0.66 (± 5.53)	-0.27 (± 6.00)		
Change from Baseline at Week 72	-0.16 (± 6.25)	0.94 (± 5.57)		
Change from Baseline at Week 96	-1.90 (± 6.17)	1.86 (± 6.12)		
Change from Baseline at Week 120	-0.33 (± 4.03)	3.76 (± 6.72)		
Change from Baseline at Week 144	-0.95 (± 5.66)	5.20 (± 7.11)		
Change from Baseline at Week 168	-5.23 (± 7.41)	3.06 (± 6.99)		
Change from Baseline at Week 192	0000 (± 0000)	1.19 (± 5.04)		
Change from Baseline at Week 216	0000 (± 0000)	-2.38 (± 0000)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in SF-36 Mental Health Domain Scores at 24 Week Intervals During the DB Period

End point title	Change from Baseline in SF-36 Mental Health Domain Scores at 24 Week Intervals During the DB Period

End point description:

The SF-36v2 is a multi-purpose, short form health survey with 36 questions. It has 8 domains (vitality, physical functioning, bodily pain, general health, role-physical, role emotional, social role functioning and mental health) of functional health and well-being scores as well as psychometrically based physical and mental health component summary measures and a preference-based health utility index. The domain scores were transformed to a 0-100 scale, where higher scores indicate better quality of life. A positive change from baseline indicates an improvement.

End point type	Secondary

End point timeframe:

Baseline up to Week 216

End point values	Placebo + Baseline Treatment	Satralizumab + Baseline Treatment		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	41		
Units: score on scale				
arithmetic mean (standard deviation)				
Baseline	43.71 (± 10.92)	43.59 (± 10.55)		
Change from Baseline at Week 24	5.23 (± 7.69)	0.99 (± 10.21)		
Change from Baseline at Week 48	2.76 (± 8.54)	0.11 (± 10.73)		
Change from Baseline at Week 72	5.23 (± 7.66)	3.18 (± 9.72)		
Change from Baseline at Week 96	4.09 (± 8.49)	2.12 (± 8.13)		
Change from Baseline at Week 120	3.14 (± 7.06)	1.57 (± 6.76)		
Change from Baseline at Week 144	3.49 (± 7.04)	4.88 (± 8.38)		
Change from Baseline at Week 168	4.36 (± 3.02)	4.07 (± 10.72)		
Change from Baseline at Week 192	0000 (± 0000)	13.09 (± 14.80)		
Change from Baseline at Week 216	0000 (± 0000)	23.55 (± 0000)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in SF-36 Physical Functioning Domain Scores at 24 Week Intervals During the DB Period

End point title	Change from Baseline in SF-36 Physical Functioning Domain Scores at 24 Week Intervals During the DB Period

End point description:

The SF-36v2 is a multi-purpose, short form health survey with 36 questions. It has 8 domains (vitality, physical functioning, bodily pain, general health, role-physical, role emotional, social role functioning and mental health) of functional health and well-being scores as well as psychometrically based physical and mental health component summary measures and a preference-based health utility index. The domain scores were transformed to a 0-100 scale, where higher scores indicate better quality of life. A positive change from baseline indicates an improvement.

End point type	Secondary

End point timeframe:

Baseline up to Week 216

End point values	Placebo + Baseline Treatment	Satralizumab + Baseline Treatment		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	41		
Units: score on scale				
arithmetic mean (standard deviation)				
Baseline	42.50 (± 10.53)	43.46 (± 10.34)		
Change from Baseline at Week 24	3.56 (± 7.04)	1.49 (± 7.05)		
Change from Baseline at Week 48	1.92 (± 4.30)	1.86 (± 7.73)		

Change from Baseline at Week 72	3.19 (± 6.54)	0.88 (± 6.52)		
Change from Baseline at Week 96	0.84 (± 6.77)	2.37 (± 7.75)		
Change from Baseline at Week 120	-0.19 (± 8.39)	2.58 (± 6.03)		
Change from Baseline at Week 144	2.55 (± 4.06)	3.32 (± 5.72)		
Change from Baseline at Week 168	1.92 (± 5.06)	0.00 (± 5.50)		
Change from Baseline at Week 192	0000 (± 0000)	1.91 (± 2.70)		
Change from Baseline at Week 216	0000 (± 0000)	1.91 (± 0000)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in SF-36 Role-Emotional Domain Scores at 24 Week Intervals During the DB Period

End point title	Change from Baseline in SF-36 Role-Emotional Domain Scores at 24 Week Intervals During the DB Period

End point description:

The SF-36v2 is a multi-purpose, short form health survey with 36 questions. It has 8 domains (vitality, physical functioning, bodily pain, general health, role-physical, role emotional, social role functioning and mental health) of functional health and well-being scores as well as psychometrically based physical and mental health component summary measures and a preference-based health utility index. The domain scores were transformed to a 0-100 scale, where higher scores indicate better quality of life. A positive change from baseline indicates an improvement.

End point type	Secondary

End point timeframe:

Baseline up to Week 216

End point values	Placebo + Baseline Treatment	Satralizumab + Baseline Treatment		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	41		
Units: score on scale				
arithmetic mean (standard deviation)				
Baseline	43.98 (± 11.46)	43.01 (± 10.55)		
Change from Baseline at Week 24	2.24 (± 10.35)	0.36 (± 10.12)		
Change from Baseline at Week 48	3.29 (± 8.05)	0.00 (± 12.49)		
Change from Baseline at Week 72	1.39 (± 9.38)	2.57 (± 7.66)		
Change from Baseline at Week 96	4.13 (± 14.40)	0.83 (± 10.20)		
Change from Baseline at Week 120	3.13 (± 12.44)	0.35 (± 6.95)		
Change from Baseline at Week 144	3.09 (± 9.61)	3.25 (± 7.38)		
Change from Baseline at Week 168	1.16 (± 5.32)	4.64 (± 9.05)		
Change from Baseline at Week 192	0000 (± 0000)	12.19 (± 2.46)		
Change from Baseline at Week 216	0000 (± 0000)	6.97 (± 0000)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in SF-36 Role-Physical Domain Scores at 24 Week Intervals During the DB Period

End point title	Change from Baseline in SF-36 Role-Physical Domain Scores at 24 Week Intervals During the DB Period

End point description:

The SF-36v2 is a multi-purpose, short form health survey with 36 questions. It has 8 domains (vitality, physical functioning, bodily pain, general health, role-physical, role emotional, social role functioning and mental health) of functional health and well-being scores as well as psychometrically based physical and mental health component summary measures and a preference-based health utility index. The domain scores were transformed to a 0-100 scale, where higher scores indicate better quality of life. A positive change from baseline indicates an improvement.

End point type	Secondary

End point timeframe:

Baseline up to Week 216

End point values	Placebo + Baseline Treatment	Satralizumab + Baseline Treatment		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	41		
Units: score on scale				
arithmetic mean (standard deviation)				
Baseline	40.74 (± 10.12)	41.88 (± 11.38)		
Change from Baseline at Week 24	3.93 (± 9.56)	3.02 (± 6.95)		
Change from Baseline at Week 48	1.37 (± 7.23)	1.40 (± 8.66)		
Change from Baseline at Week 72	2.40 (± 7.94)	2.83 (± 7.81)		
Change from Baseline at Week 96	0.42 (± 9.03)	1.71 (± 4.60)		
Change from Baseline at Week 120	1.57 (± 9.47)	3.14 (± 7.44)		
Change from Baseline at Week 144	2.99 (± 6.05)	2.69 (± 6.80)		
Change from Baseline at Week 168	3.74 (± 10.61)	2.25 (± 6.45)		
Change from Baseline at Week 192	0000 (± 0000)	4.49 (± 6.35)		
Change from Baseline at Week 216	0000 (± 0000)	8.98 (± 0000)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in SF-36 Social Role Functioning Domain Scores at 24 Week Intervals During the DB Period

End point title	Change from Baseline in SF-36 Social Role Functioning Domain Scores at 24 Week Intervals During the DB Period

End point description:

The SF-36v2 is a multi-purpose, short form health survey with 36 questions. It has 8 domains (vitality, physical functioning, bodily pain, general health, role-physical, role emotional, social role functioning and mental health) of functional health and well-being scores as well as psychometrically based physical and mental health component summary measures and a preference-based health utility index. The

domain scores were transformed to a 0-100 scale, where higher scores indicate better quality of life. A positive change from baseline indicates an improvement.

End point type	Secondary

End point timeframe:

Baseline up to Week 216

End point values	Placebo + Baseline Treatment	Satralizumab + Baseline Treatment		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	41		
Units: score on scale				
arithmetic mean (standard deviation)				
Baseline	41.70 (± 11.62)	44.26 (± 10.92)		
Change from Baseline at Week 24	1.73 (± 7.96)	0.86 (± 8.69)		
Change from Baseline at Week 48	1.12 (± 7.80)	0.00 (± 10.24)		
Change from Baseline at Week 72	2.34 (± 7.78)	2.18 (± 7.22)		
Change from Baseline at Week 96	2.82 (± 11.72)	0.00 (± 9.38)		
Change from Baseline at Week 120	1.51 (± 13.59)	0.25 (± 9.13)		
Change from Baseline at Week 144	0.56 (± 9.85)	2.01 (± 7.29)		
Change from Baseline at Week 168	1.67 (± 22.61)	0.00 (± 5.61)		
Change from Baseline at Week 192	0000 (± 0000)	0.00 (± 0.00)		
Change from Baseline at Week 216	0000 (± 0000)	-5.01 (± 0000)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in SF-36 Vitality Domain Scores at 24 Week Intervals During the DB Period

End point title	Change from Baseline in SF-36 Vitality Domain Scores at 24 Week Intervals During the DB Period

End point description:

The SF-36v2 is a multi-purpose, short form health survey with 36 questions. It has 8 domains (vitality, physical functioning, bodily pain, general health, role-physical, role emotional, social role functioning and mental health) of functional health and well-being scores as well as psychometrically based physical and mental health component summary measures and a preference-based health utility index. The domain scores were transformed to a 0-100 scale, where higher scores indicate better quality of life. A positive change from baseline indicates an improvement.

End point type	Secondary

End point timeframe:

Baseline up to Week 216

End point values	Placebo + Baseline Treatment	Satralizumab + Baseline Treatment		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	41		
Units: score on scale				
arithmetic mean (standard deviation)				
Baseline	45.95 (± 9.14)	46.66 (± 9.65)		
Change from Baseline at Week 24	2.66 (± 7.38)	1.74 (± 8.61)		
Change from Baseline at Week 48	1.65 (± 5.60)	-0.25 (± 8.71)		
Change from Baseline at Week 72	4.55 (± 6.91)	1.38 (± 9.12)		
Change from Baseline at Week 96	4.08 (± 8.53)	2.41 (± 8.28)		
Change from Baseline at Week 120	2.97 (± 5.24)	2.67 (± 8.45)		
Change from Baseline at Week 144	3.96 (± 6.12)	4.16 (± 10.03)		
Change from Baseline at Week 168	2.97 (± 2.97)	0.99 (± 10.82)		
Change from Baseline at Week 192	0000 (± 0000)	7.43 (± 10.51)		
Change from Baseline at Week 216	0000 (± 0000)	11.89 (± 0000)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in EuroQoL-5 Dimensions (EQ-5D) Index Scores at 24 Week Intervals During the DB Period

End point title	Change from Baseline in EuroQoL-5 Dimensions (EQ-5D) Index Scores at 24 Week Intervals During the DB Period

End point description:

The EQ-5D is a participant-answered questionnaire measuring 5 dimensions of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression with 3 possible response categories: 1) no problems; 2) some problems; 3) severe problems. The scores from 5 dimensions are used as input to generate EQ-5D index score using scoring algorithm. The EQ-5D index score is scored on a scale of -0.2 to 1. A higher score reflects a better health state. A positive change from baseline indicates an improvement.

End point type	Secondary

End point timeframe:

Baseline up to Week 216

End point values	Placebo + Baseline Treatment	Satralizumab + Baseline Treatment		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	40		
Units: score on scale				
arithmetic mean (standard deviation)				
Baseline	0.7297 (± 0.1863)	0.7634 (± 0.1811)		
Change from Baseline at Week 24	0.0649 (± 0.1596)	-0.0082 (± 0.1882)		
Change from Baseline at Week 48	0.0352 (± 0.1830)	0.0011 (± 0.1256)		

Change from Baseline at Week 72	0.0724 (± 0.2088)	0.0241 (± 0.1084)		
Change from Baseline at Week 96	0.0349 (± 0.1758)	0.0167 (± 0.1056)		
Change from Baseline at Week 120	0.0336 (± 0.2111)	0.0257 (± 0.1178)		
Change from Baseline at Week 144	0.0846 (± 0.1650)	0.0488 (± 0.1424)		
Change from Baseline at Week 168	0.0648 (± 0.1031)	0.0307 (± 0.1335)		
Change from Baseline at Week 192	0000 (± 0000)	0.1873 (± 0.2890)		
Change from Baseline at Week 216	0000 (± 0000)	0.3322 (± 0000)		

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Satralizumab Concentration During the DB Period

End point title	Serum Satralizumab Concentration During the DB Period

End point description:

End point type	Secondary

End point timeframe:

Baseline, Weeks 2, 4, 5, 6, 8, and every 4 weeks thereafter up to Week 224

End point values	Satralizumab + Baseline Treatment			
Subject group type	Subject analysis set			
Number of subjects analysed	41			
Units: ng/mL				
arithmetic mean (standard deviation)				
Baseline	100.00 (± 0.00)			
Week 2	11343.66 (± 5125.84)			
Week 4	22222.63 (± 8003.48)			
Week 5	28461.00 (± 12542.52)			
Week 6	28174.50 (± 11199.00)			
Week 8	21246.92 (± 9045.31)			
Week 12	20927.63 (± 9536.07)			
Week 16	20274.86 (± 10694.38)			
Week 20	20146.06 (± 10740.65)			

Week 24	20189.00 (± 10140.88)			
Week 28	20826.07 (± 10995.92)			
Week 32	20631.79 (± 11110.94)			
Week 36	21114.62 (± 11190.52)			
Week 40	22224.76 (± 13389.71)			
Week 44	22582.17 (± 12031.13)			
Week 48	23324.80 (± 13979.87)			
Week 52	24570.83 (± 15798.38)			
Week 56	24252.50 (± 15433.80)			
Week 60	23061.67 (± 15777.82)			
Week 64	23369.55 (± 13447.96)			
Week 68	26194.43 (± 16836.77)			
Week 72	26618.87 (± 14999.38)			
Week 76	26539.09 (± 13736.30)			
Week 80	26868.00 (± 14005.87)			
Week 84	27037.62 (± 15460.97)			
Week 88	26203.00 (± 14309.81)			
Week 92	28308.10 (± 15111.34)			
Week 96	26754.43 (± 15146.20)			
Week 100	27707.14 (± 14225.93)			
Week 104	26203.81 (± 13616.28)			
Week 108	26112.38 (± 12521.65)			
Week 112	24925.10 (± 12181.81)			
Week 116	26360.50 (± 13885.76)			
Week 120	24910.00 (± 13217.57)			
Week 124	24689.50 (± 14352.30)			
Week 128	22395.53 (± 12954.00)			
Week 132	23804.74 (± 14878.32)			
Week 136	25856.32 (± 15506.85)			
Week 140	26118.56 (± 15264.89)			
Week 144	27975.33 (± 11536.28)			

Week 148	27935.83 (± 11940.90)			
Week 152	28967.00 (± 10354.22)			
Week 156	27990.00 (± 10444.75)			
Week 160	28983.33 (± 11429.02)			
Week 164	28903.33 (± 10780.69)			
Week 168	23683.33 (± 11615.40)			
Week 172	24498.89 (± 11106.23)			
Week 176	26300.00 (± 11498.48)			
Week 180	28300.00 (± 9431.86)			
Week 184	32380.00 (± 9427.19)			
Week 188	36600.00 (± 8214.62)			
Week 192	32650.00 (± 7848.89)			
Week 196	30800.00 (± 4808.33)			
Week 200	28400.00 (± 3818.38)			
Week 204	25300.00 (± 3252.69)			
Week 208	25900.00 (± 0000)			
Week 212	17000.00 (± 0000)			
Week 216	28600.00 (± 0000)			
Week 220	31600.00 (± 0000)			
Week 224	28700.00 (± 0000)			

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Soluble IL-6 Receptor (sIL-6R) Concentration During the DB Period

End point title	Serum Soluble IL-6 Receptor (sIL-6R) Concentration During the DB Period

End point description:

End point type	Secondary

End point timeframe:

Baseline, Weeks 2, 4, and every 4 weeks thereafter up to Week 224

End point values	Placebo + Baseline Treatment	Satralizumab + Baseline Treatment		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	41		
Units: ng/mL				
arithmetic mean (standard deviation)				
Baseline	32.52 (± 7.78)	35.13 (± 21.52)		
Week 2	33.82 (± 8.30)	437.41 (± 72.31)		
Week 4	33.13 (± 8.52)	572.29 (± 94.84)		
Week 8	34.02 (± 9.43)	642.92 (± 115.51)		
Week 12	32.58 (± 8.52)	651.41 (± 99.20)		
Week 16	32.67 (± 9.32)	640.57 (± 97.41)		
Week 20	34.22 (± 8.15)	636.64 (± 109.75)		
Week 24	34.44 (± 9.31)	639.20 (± 108.94)		
Week 28	33.70 (± 8.28)	649.11 (± 131.85)		
Week 32	33.48 (± 8.74)	651.82 (± 162.04)		
Week 36	34.39 (± 11.01)	652.12 (± 124.70)		
Week 40	33.31 (± 7.86)	664.21 (± 158.61)		
Week 44	33.94 (± 7.77)	677.13 (± 173.99)		
Week 48	34.50 (± 9.14)	627.23 (± 217.06)		
Week 52	44.01 (± 44.26)	656.29 (± 173.67)		
Week 56	37.00 (± 7.42)	626.83 (± 155.56)		
Week 60	36.39 (± 7.81)	617.00 (± 142.13)		
Week 64	35.14 (± 8.78)	621.27 (± 152.45)		
Week 68	35.35 (± 8.68)	664.91 (± 130.58)		
Week 72	36.02 (± 10.73)	648.83 (± 134.32)		
Week 76	36.94 (± 9.46)	643.91 (± 118.60)		
Week 80	36.45 (± 9.50)	667.24 (± 133.49)		
Week 84	34.60 (± 8.88)	649.38 (± 137.64)		
Week 88	31.95 (± 8.29)	651.35 (± 150.58)		
Week 92	34.30 (± 9.71)	633.43 (± 134.36)		

Week 96	32.88 (± 9.39)	630.62 (± 162.28)		
Week 100	33.78 (± 9.04)	651.90 (± 162.09)		
Week 104	31.61 (± 9.13)	649.57 (± 185.99)		
Week 108	31.49 (± 9.23)	658.67 (± 152.61)		
Week 112	32.75 (± 7.77)	683.90 (± 135.07)		
Week 116	33.68 (± 8.31)	653.98 (± 194.92)		
Week 120	33.73 (± 6.20)	667.10 (± 152.24)		
Week 124	33.06 (± 9.31)	696.45 (± 138.17)		
Week 128	34.07 (± 8.83)	670.05 (± 138.28)		
Week 132	34.28 (± 4.95)	671.84 (± 138.75)		
Week 136	32.43 (± 8.12)	674.95 (± 170.04)		
Week 140	32.97 (± 6.52)	645.72 (± 132.32)		
Week 144	35.37 (± 8.91)	699.80 (± 101.84)		
Week 148	37.97 (± 12.40)	672.42 (± 107.40)		
Week 152	35.08 (± 9.08)	701.60 (± 110.27)		
Week 156	36.92 (± 7.77)	720.33 (± 103.58)		
Week 160	40.38 (± 7.31)	704.89 (± 109.86)		
Week 164	43.08 (± 10.54)	723.67 (± 136.20)		
Week 168	42.30 (± 5.92)	744.22 (± 123.47)		
Week 172	42.03 (± 5.87)	706.33 (± 127.63)		
Week 176	39.85 (± 6.15)	730.56 (± 121.75)		
Week 180	38.85 (± 12.09)	769.83 (± 119.50)		
Week 184	0000 (± 0000)	736.80 (± 152.09)		
Week 188	0000 (± 0000)	853.67 (± 38.02)		
Week 192	0000 (± 0000)	930.00 (± 49.50)		
Week 196	0000 (± 0000)	887.00 (± 91.92)		
Week 200	0000 (± 0000)	902.50 (± 79.90)		
Week 204	0000 (± 0000)	935.00 (± 7.07)		
Week 208	0000 (± 0000)	941.00 (± 0000)		
Week 212	0000 (± 0000)	971.00 (± 0000)		
Week 216	0000 (± 0000)	896.00 (± 0000)		

Week 220	0000 (± 0000)	901.00 (± 0000)		
Week 224	0000 (± 0000)	831.00 (± 0000)		

Statistical analyses

No statistical analyses for this end point

Secondary: Serum High Sensitivity C-Reactive Protein (hsCRP) Concentration During the DB Period

End point title	Serum High Sensitivity C-Reactive Protein (hsCRP) Concentration During the DB Period

End point description:

End point type	Secondary

End point timeframe:

Baseline, Weeks 2, 4, and every 4 weeks thereafter up to Week 224

End point values	Placebo + Baseline Treatment	Satralizumab + Baseline Treatment		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	41		
Units: mg/L				
arithmetic mean (standard deviation)				
Baseline	1.48 (± 2.08)	1.68 (± 2.49)		
Week 2	1.65 (± 2.86)	0.78 (± 2.93)		
Week 4	1.59 (± 2.27)	0.44 (± 0.72)		
Week 8	1.76 (± 2.25)	0.59 (± 1.26)		
Week 12	1.48 (± 2.07)	0.47 (± 0.60)		
Week 16	1.91 (± 3.34)	0.49 (± 0.51)		
Week 20	1.91 (± 3.44)	0.48 (± 0.50)		
Week 24	2.45 (± 6.87)	0.58 (± 0.91)		
Week 28	1.96 (± 3.24)	0.73 (± 1.34)		
Week 32	2.36 (± 4.96)	0.73 (± 1.21)		
Week 36	2.48 (± 3.59)	0.56 (± 0.66)		
Week 40	2.49 (± 4.53)	1.13 (± 2.26)		
Week 44	1.41 (± 1.47)	0.72 (± 1.20)		
Week 48	1.59 (± 2.07)	0.86 (± 1.44)		
Week 52	2.60 (± 3.87)	0.67 (± 0.88)		
Week 56	1.43 (± 1.58)	0.72 (± 1.02)		
Week 60	2.63 (± 4.34)	1.05 (± 2.15)		
Week 64	11.10 (± 40.09)	0.64 (± 0.89)		
Week 68	1.86 (± 2.66)	0.57 (± 0.47)		
Week 72	3.80 (± 8.83)	0.59 (± 0.71)		
Week 76	5.24 (± 10.68)	0.51 (± 0.37)		

Week 80	2.11 (± 2.63)	0.58 (± 0.51)		
Week 84	2.08 (± 2.26)	0.59 (± 0.61)		
Week 88	5.19 (± 12.83)	0.60 (± 0.53)		
Week 92	2.07 (± 2.21)	0.60 (± 0.70)		
Week 96	2.92 (± 4.60)	0.74 (± 1.01)		
Week 100	2.58 (± 4.53)	0.87 (± 1.49)		
Week 104	1.41 (± 2.05)	0.84 (± 1.40)		
Week 108	1.93 (± 2.25)	0.66 (± 0.58)		
Week 112	1.54 (± 1.56)	0.82 (± 0.87)		
Week 116	2.39 (± 3.91)	0.84 (± 1.26)		
Week 120	1.53 (± 1.33)	0.98 (± 1.58)		
Week 124	1.43 (± 1.43)	0.72 (± 0.67)		
Week 128	6.00 (± 16.28)	0.96 (± 1.29)		
Week 132	1.08 (± 0.94)	0.70 (± 0.84)		
Week 136	1.43 (± 1.54)	0.99 (± 1.68)		
Week 140	1.15 (± 1.28)	1.06 (± 2.25)		
Week 144	0.82 (± 0.73)	0.44 (± 0.37)		
Week 148	1.29 (± 1.43)	0.35 (± 0.18)		
Week 152	1.08 (± 0.97)	0.38 (± 0.23)		
Week 156	1.52 (± 1.42)	0.35 (± 0.18)		
Week 160	0.83 (± 0.53)	0.37 (± 0.22)		
Week 164	3.18 (± 4.89)	0.38 (± 0.20)		
Week 168	0.80 (± 0.26)	0.40 (± 0.19)		
Week 172	1.37 (± 1.00)	0.26 (± 0.17)		
Week 176	0.95 (± 0.64)	0.31 (± 0.19)		
Week 180	30.15 (± 41.65)	0.28 (± 0.15)		
Week 184	0000 (± 0000)	0.20 (± 0.11)		
Week 188	0000 (± 0000)	0.37 (± 0.06)		
Week 192	0000 (± 0000)	0.15 (± 0.00)		
Week 196	0000 (± 0000)	0.23 (± 0.11)		
Week 200	0000 (± 0000)	0.23 (± 0.11)		
Week 204	0000 (± 0000)	0.23 (± 0.11)		
Week 208	0000 (± 0000)	0.30 (± 0000)		
Week 212	0000 (± 0000)	0.40 (± 0000)		
Week 216	0000 (± 0000)	0.30 (± 0000)		
Week 220	0000 (± 0000)	0.40 (± 0000)		
Week 224	0000 (± 0000)	0.15 (± 0000)		

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Interleukin-6 (IL-6) Concentration During the DB Period

End point title	Serum Interleukin-6 (IL-6) Concentration During the DB Period
End point description:	
End point type	Secondary

End point timeframe:
Baseline, Weeks 2, 4, and every 4 weeks thereafter up to Week 224

End point values	Placebo + Baseline Treatment	Satralizumab + Baseline Treatment		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	41		
Units: pg/mL				
arithmetic mean (standard deviation)				
Baseline	1.63 (± 0.39)	1.92 (± 1.36)		
Week 2	1.84 (± 0.95)	40.12 (± 118.83)		
Week 4	2.33 (± 2.99)	28.30 (± 31.31)		
Week 8	1.69 (± 0.55)	32.37 (± 77.99)		
Week 12	1.71 (± 0.60)	22.95 (± 20.55)		
Week 16	1.84 (± 0.90)	25.76 (± 30.85)		
Week 20	2.99 (± 5.45)	23.07 (± 15.37)		
Week 24	2.02 (± 1.52)	21.53 (± 17.91)		
Week 28	1.95 (± 1.38)	25.14 (± 24.27)		
Week 32	1.74 (± 0.84)	23.77 (± 18.53)		
Week 36	2.13 (± 1.41)	23.08 (± 15.56)		
Week 40	1.66 (± 0.40)	27.31 (± 47.45)		
Week 44	1.57 (± 0.00)	17.01 (± 15.38)		
Week 48	1.69 (± 0.53)	19.45 (± 19.36)		
Week 52	2.12 (± 1.36)	21.11 (± 17.42)		
Week 56	1.57 (± 0.00)	21.74 (± 20.96)		
Week 60	2.27 (± 1.46)	23.25 (± 23.36)		
Week 64	2.46 (± 3.22)	24.31 (± 20.74)		
Week 68	1.94 (± 1.14)	31.30 (± 53.79)		
Week 72	1.93 (± 0.97)	24.69 (± 24.45)		
Week 76	2.21 (± 1.87)	20.45 (± 13.79)		
Week 80	2.19 (± 2.51)	23.29 (± 19.64)		
Week 84	2.66 (± 2.36)	22.71 (± 21.49)		
Week 88	2.59 (± 2.77)	29.17 (± 25.58)		

Week 92	1.84 (± 0.77)	24.51 (± 32.02)		
Week 96	3.06 (± 3.19)	21.52 (± 20.20)		
Week 100	2.04 (± 1.02)	21.77 (± 24.98)		
Week 104	1.95 (± 0.96)	22.61 (± 26.55)		
Week 108	1.76 (± 0.70)	24.18 (± 20.55)		
Week 112	1.57 (± 0.00)	32.18 (± 36.15)		
Week 116	1.57 (± 0.00)	22.33 (± 22.20)		
Week 120	1.71 (± 0.52)	21.86 (± 24.54)		
Week 124	1.57 (± 0.00)	26.23 (± 27.67)		
Week 128	1.57 (± 0.00)	25.40 (± 31.20)		
Week 132	1.57 (± 0.00)	25.48 (± 27.38)		
Week 136	1.57 (± 0.00)	27.23 (± 37.56)		
Week 140	1.57 (± 0.00)	20.66 (± 18.10)		
Week 144	1.57 (± 0.00)	16.82 (± 16.16)		
Week 148	2.04 (± 1.25)	17.10 (± 11.33)		
Week 152	1.57 (± 0.00)	16.62 (± 13.75)		
Week 156	2.34 (± 1.72)	12.67 (± 5.73)		
Week 160	1.96 (± 0.80)	11.15 (± 5.12)		
Week 164	1.57 (± 0.00)	12.84 (± 6.93)		
Week 168	1.57 (± 0.00)	13.30 (± 8.89)		
Week 172	1.57 (± 0.00)	13.89 (± 6.94)		
Week 176	1.57 (± 0.00)	15.11 (± 7.16)		
Week 180	1.57 (± 0.00)	13.34 (± 6.68)		
Week 184	0000 (± 0000)	15.24 (± 9.91)		
Week 188	0000 (± 0000)	13.96 (± 9.74)		
Week 192	0000 (± 0000)	16.71 (± 13.15)		
Week 196	0000 (± 0000)	14.34 (± 12.81)		
Week 200	0000 (± 0000)	18.55 (± 8.84)		
Week 204	0000 (± 0000)	18.24 (± 12.53)		
Week 208	0000 (± 0000)	9.95 (± 0000)		
Week 212	0000 (± 0000)	8.02 (± 0000)		
Week 216	0000 (± 0000)	6.45 (± 0000)		
Week 220	0000 (± 0000)	45.80 (± 0000)		
Week 224	0000 (± 0000)	34.30 (± 0000)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with at Least One Adverse Event in the DB Period

End point title	Number of Participants with at Least One Adverse Event in the DB Period

End point description:

An adverse event is any untoward medical occurrence in a participant administered a pharmaceutical product and which does not necessarily have to have a causal relationship with the treatment. An adverse event can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a pharmaceutical product, whether or not considered related to the pharmaceutical product. Pre-existing conditions which worsen during a study are also considered as adverse events.

End point type	Secondary

End point timeframe:

Up to Week 224

End point values	Placebo + Baseline Treatment	Satralizumab + Baseline Treatment		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	41		
Units: participants	40	37		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with at Least One Serious Adverse Event in the DB Period

End point title	Number of Participants with at Least One Serious Adverse Event in the DB Period

End point description:

A serious adverse event is defined as any untoward medical occurrence that, at any dose, results in death, is life threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, is a congenital anomaly/birth defect, or is medically significant or requires intervention to prevent one or other of the outcomes listed above.

End point type	Secondary

End point timeframe:

Up to Week 224

End point values	Placebo + Baseline Treatment	Satralizumab + Baseline Treatment		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	41		
Units: participants	9	7		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Selected Adverse Events in the DB Period

End point title	Number of Participants with Selected Adverse Events in the DB Period

End point description:

Selected adverse events for this study included: 1) non-serious infections that required treatments with intravenous (IV) antibiotic, antifungal, antiviral, 2) opportunistic infections that required treatments with oral antibiotics, antifungals, or antivirals, 3) injection-related reactions (IRRs; an AE which occured within 24 hours after study treatment injection except where the event was not considered an allergic reaction), and 4) anaphylaxis (an acute allergic/hypersensitivity reaction).

End point type	Secondary

End point timeframe:

Up to Week 224

End point values	Placebo + Baseline Treatment	Satralizumab + Baseline Treatment		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	41		
Units: participants				
Non serious Infections requiring IV treatment	4	1		
Potential Opportunistic Infections	5	4		
Injection Related Reactions	2	5		
Anaphylaxis	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Non-Serious Adverse Events of Special Interest in the DB Period

End point title	Number of Participants with Non-Serious Adverse Events of Special Interest in the DB Period

End point description:

Non-serious adverse events of special interest for this study included: 1) cases of an elevated alanine aminotransferase (ALT) or aspartate aminotransferase (AST) in combination with either an elevated bilirubin or clinical jaundice, 2) suspected transmission of an infectious agent by the study treatment.

End point type	Secondary

End point timeframe:

Up to Week 224

End point values	Placebo + Baseline Treatment	Satralizumab + Baseline Treatment		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	41		
Units: participants	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Suicidal Behaviors and Ideations Collected by Columbia-Suicide Severity Rating Scale in the DB Period

End point title	Number of Participants With Suicidal Behaviors and Ideations Collected by Columbia-Suicide Severity Rating Scale in the DB Period

End point description:

The Columbia-Suicide Severity Rating Scale (C-SSRS) is an assessment tool to evaluate suicidal ideation and behavior. Categories have binary responses (yes/no) and include: Wish to be Dead; Non-specific Active Suicidal Thoughts; Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act; Active Suicidal Ideation with Some Intent to Act, without Specific Plan; Active Suicidal Ideation with Specific Plan and Intent, Preparatory Acts and Behavior; Aborted Attempt; Interrupted Attempt; Actual Attempt (non-fatal); Completed Suicide. Suicidal ideation or behavior is indicated by a "yes" answer to any of the listed categories. A score of 0 is assigned if no suicide risk is present. A score of 1 or higher indicates suicidal ideation or behavior.

End point type	Secondary

End point timeframe:

Baseline and Post-Baseline (up to Week 224)

End point values	Placebo + Baseline Treatment	Satralizumab + Baseline Treatment		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	41	41		
Units: participants				
Baseline	5	12		
Post-Baseline	2	3		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Anti-Drug Antibodies to Satralizumab in the DB Period

End point title	Percentage of Participants with Anti-Drug Antibodies to Satralizumab in the DB Period

End point description:

Reported here is the percentage of participants with at least one positive anti-drug antibody measurement during the DB period.

End point type	Secondary

End point timeframe:

Up to approximately Week 224

End point values	Satralizumab + Baseline Treatment			
Subject group type	Subject analysis set			
Number of subjects analysed	41			
Units: percentage				
number (not applicable)	41.5			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Anti-Drug Antibodies to Satralizumab Overall S237 period

End point title	Percentage of Participants with Anti-Drug Antibodies to Satralizumab Overall S237 period

End point description:

Reported here is the percentage of participants with at least one positive anti-drug antibody measurement during Overall S237 period. Participants from SAF who received satralizumab were evaluated for this outcome measure. The SAF included all randomized participants who had received at least 1 dose of satralizumab or placebo. Data was summarized together for this outcome measure.

End point type	Secondary

End point timeframe:

Up to approximately Week 368

End point values	Satralizumab + Baseline Treatment			
Subject group type	Subject analysis set			
Number of subjects analysed	75			
Units: Percentage of participants				
number (not applicable)				
Treatment-Boosted ADA Patients	2.7			

Treatment-Induced ADA Patients	44.0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to clinical cut-off date, 23-Dec-2021

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	Satralizumab + Baseline Treatment Double Blind period

Reporting group description:

Participants randomized to this arm for the double-blind period received satralizumab in addition to baseline treatment. The double-blind period ends when either the participant has a treated relapse or the total number of protocol-defined relapses confirmed by the Clinical Endpoint Committee (CEC) reaches 26.

Reporting group title	Placebo + Baseline Treatment Double Blind Period

Reporting group description:

Participants randomized to this arm for the double-blind period received placebo in addition to baseline treatment. The double-blind period ends when either the participant has a treated relapse or the total number of protocol-defined relapses confirmed by the Clinical Endpoint Committee (CEC) reaches 26.

Reporting group title	Satralizumab + Baseline Treatment Open Label period

Reporting group description:

In the open-label extension period, the participant received (with or without baseline treatment) an SC injection of satralizumab at Weeks 0, 2, and 4, and Q4W thereafter, with the last study drug administration on or before 31 December 2021

Reporting group title	Satralizumab Open-Label Period

Reporting group description:

Participant was directly enrolled into the OLE to receive natalizumab. In the open-label extension period, the participant received (with or without baseline treatment) an SC injection of satralizumab at Weeks 0, 2, and 4, and Q4W thereafter.

Reporting group title	Placebo + Baseline Treatment Open Label Period

Reporting group description:

In the open-label extension period, the participant received (with or without baseline treatment) an SC injection of satralizumab at Weeks 0, 2, and 4, and Q4W thereafter, with the last study drug administration on or before 31 December 2021.

Serious adverse events	Satralizumab + Baseline Treatment Double Blind period	Placebo + Baseline Treatment Double Blind Period	Satralizumab + Baseline Treatment Open Label period
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 42 (21.43%)	9 / 42 (21.43%)	8 / 39 (20.51%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer			

subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 39 (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
Hepatic cancer			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 39 (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
Colon cancer metastatic			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 39 (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
Uterine leiomyoma			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	0 / 39 (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			
Femur fracture			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	0 / 39 (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
Spinal compression fracture			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm fracture			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			

Parkinsonism			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tension headache			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	0 / 39 (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
Neuromyelitis optica pseudo relapse			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 39 (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 macrocytic			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	0 / 39 (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
Leukopenia			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 39 (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
Lymphopenia			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 39 (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
Immune thrombocytopenia			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 39 (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
General disorders and administration			

site conditions			
Gait disturbance			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Glaucoma			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal vein thrombosis			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 39 (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
Cataract			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	0 / 39 (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 disorders			
Abdominal pain			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 39 (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
Pancreatitis acute			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 39 (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
Rectal haemorrhage			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 39 (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			
Cervical dysplasia			

subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine polyp			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 39 (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
Psychiatric disorders			
Suicide attempt			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	0 / 39 (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			
Dysuria			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 39 (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
Musculoskeletal and connective tissue disorders			
Systemic lupus erythematosus			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 39 (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
Lumbar spinal stenosis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 39 (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
Cellulitis			

subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 39 (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
Escherichia sepsis			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 39 (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
Hepatitis E			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 42 (2.38%)	1 / 42 (2.38%)	0 / 39 (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
Urosepsis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 39 (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
Large intestine infection			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic endocarditis			

subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 39 (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	Satralizumab Open-Label Period	Placebo + Baseline Treatment Open Label Period	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	5 / 32 (15.63%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cancer			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer metastatic			
subjects affected / exposed	0 / 1 (0.00%)	1 / 32 (3.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine leiomyoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Femur fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			

subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper limb fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Forearm fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Parkinsonism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tension headache			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuromyelitis optica pseudo relapse			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	0 / 1 (0.00%)	1 / 32 (3.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia macrocytic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukopenia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune thrombocytopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Gait disturbance			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Glaucoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal vein thrombosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Pancreatitis acute			
subjects affected / exposed	0 / 1 (0.00%)	1 / 32 (3.13%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal haemorrhage			
subjects affected / exposed	1 / 1 (100.00%)	0 / 32 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Cervical dysplasia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine polyp			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Suicide attempt			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Systemic lupus erythematosus			
subjects affected / exposed	0 / 1 (0.00%)	1 / 32 (3.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar spinal stenosis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 32 (3.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia sepsis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis E			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			

subjects affected / exposed	0 / 1 (0.00%)	1 / 32 (3.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic endocarditis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 32 (3.13%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Satralizumab + Baseline Treatment Double Blind period	Placebo + Baseline Treatment Double Blind Period	Satralizumab + Baseline Treatment Open Label period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	35 / 42 (83.33%)	37 / 42 (88.10%)	30 / 39 (76.92%)
Vascular disorders			
Flushing			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	2 / 39 (5.13%)
occurrences (all)	1	0	2
Hypertension			
subjects affected / exposed	3 / 42 (7.14%)	0 / 42 (0.00%)	2 / 39 (5.13%)
occurrences (all)	4	0	7
Hypotension			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	2 / 42 (4.76%)	1 / 42 (2.38%)	0 / 39 (0.00%)
occurrences (all)	2	1	0
Pyrexia			
subjects affected / exposed	0 / 42 (0.00%)	5 / 42 (11.90%)	0 / 39 (0.00%)
occurrences (all)	0	7	0

Non-cardiac chest pain			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	1 / 39 (2.56%)
occurrences (all)	0	1	1
Immune system disorders			
Hypocomplementaemia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	5
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 42 (2.38%)	2 / 42 (4.76%)	3 / 39 (7.69%)
occurrences (all)	2	3	3
Oropharyngeal pain			
subjects affected / exposed	3 / 42 (7.14%)	1 / 42 (2.38%)	2 / 39 (5.13%)
occurrences (all)	4	1	2
Rhinorrhoea			
subjects affected / exposed	1 / 42 (2.38%)	1 / 42 (2.38%)	2 / 39 (5.13%)
occurrences (all)	1	1	3
Psychiatric disorders			
Anxiety			
subjects affected / exposed	2 / 42 (4.76%)	1 / 42 (2.38%)	2 / 39 (5.13%)
occurrences (all)	2	1	2
Insomnia			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	1 / 39 (2.56%)
occurrences (all)	1	0	1
Depression			
subjects affected / exposed	1 / 42 (2.38%)	1 / 42 (2.38%)	0 / 39 (0.00%)
occurrences (all)	1	1	0
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 42 (2.38%)	3 / 42 (7.14%)	1 / 39 (2.56%)
occurrences (all)	1	4	1
Lymphocyte count decreased			

subjects affected / exposed	1 / 42 (2.38%)	2 / 42 (4.76%)	1 / 39 (2.56%)
occurrences (all)	1	2	1
Alanine aminotransferase increased			
subjects affected / exposed	1 / 42 (2.38%)	2 / 42 (4.76%)	5 / 39 (12.82%)
occurrences (all)	1	2	5
Blood fibrinogen decreased			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	2
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 42 (2.38%)	2 / 42 (4.76%)	1 / 39 (2.56%)
occurrences (all)	1	3	1
Blood fibrinogen increased			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	2 / 39 (5.13%)
occurrences (all)	0	1	2
Blood pressure increased			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	3
Neutrophil count decreased			
subjects affected / exposed	2 / 42 (4.76%)	0 / 42 (0.00%)	1 / 39 (2.56%)
occurrences (all)	2	0	2
Prothrombin time prolonged			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	2
White blood cell count decreased			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	1 / 39 (2.56%)
occurrences (all)	1	0	2
Blood cholesterol increased			
subjects affected / exposed	2 / 42 (4.76%)	0 / 42 (0.00%)	0 / 39 (0.00%)
occurrences (all)	2	0	0
Haemoglobin decreased			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	1 / 39 (2.56%)
occurrences (all)	1	0	2
Lymphocyte percentage decreased			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0

Lymphocyte percentage increased			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Monocyte count increased			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	2
Neutrophil percentage increased			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Platelet count increased			
subjects affected / exposed	0 / 42 (0.00%)	2 / 42 (4.76%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
White blood cell count increased			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	1 / 39 (2.56%)
occurrences (all)	0	1	1
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 42 (0.00%)	2 / 42 (4.76%)	2 / 39 (5.13%)
occurrences (all)	0	2	2
Ligament sprain			
subjects affected / exposed	1 / 42 (2.38%)	1 / 42 (2.38%)	0 / 39 (0.00%)
occurrences (all)	1	1	0
Thermal burn			
subjects affected / exposed	1 / 42 (2.38%)	3 / 42 (7.14%)	2 / 39 (5.13%)
occurrences (all)	1	3	2
Rib fracture			
subjects affected / exposed	1 / 42 (2.38%)	1 / 42 (2.38%)	2 / 39 (5.13%)
occurrences (all)	1	1	2
Nervous system disorders			
Dizziness			
subjects affected / exposed	2 / 42 (4.76%)	1 / 42 (2.38%)	1 / 39 (2.56%)
occurrences (all)	3	1	1
Headache			

subjects affected / exposed	10 / 42 (23.81%)	4 / 42 (9.52%)	6 / 39 (15.38%)
occurrences (all)	28	6	10
Hypoaesthesia			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 42 (7.14%)	5 / 42 (11.90%)	5 / 39 (12.82%)
occurrences (all)	3	8	7
Iron deficiency anaemia			
subjects affected / exposed	2 / 42 (4.76%)	1 / 42 (2.38%)	1 / 39 (2.56%)
occurrences (all)	3	1	2
Leukopenia			
subjects affected / exposed	6 / 42 (14.29%)	4 / 42 (9.52%)	4 / 39 (10.26%)
occurrences (all)	10	12	10
Lymphopenia			
subjects affected / exposed	3 / 42 (7.14%)	4 / 42 (9.52%)	4 / 39 (10.26%)
occurrences (all)	7	9	14
Neutropenia			
subjects affected / exposed	2 / 42 (4.76%)	2 / 42 (4.76%)	2 / 39 (5.13%)
occurrences (all)	3	3	5
Ear and labyrinth disorders			
Ear discomfort			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	2
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	3 / 39 (7.69%)
occurrences (all)	1	0	3
Blepharitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	2
Gastrointestinal disorders			

Abdominal pain upper			
subjects affected / exposed	1 / 42 (2.38%)	1 / 42 (2.38%)	1 / 39 (2.56%)
occurrences (all)	1	1	1
Constipation			
subjects affected / exposed	2 / 42 (4.76%)	7 / 42 (16.67%)	2 / 39 (5.13%)
occurrences (all)	2	8	3
Dental caries			
subjects affected / exposed	2 / 42 (4.76%)	2 / 42 (4.76%)	2 / 39 (5.13%)
occurrences (all)	2	2	2
Diarrhoea			
subjects affected / exposed	1 / 42 (2.38%)	3 / 42 (7.14%)	3 / 39 (7.69%)
occurrences (all)	3	3	5
Gastritis			
subjects affected / exposed	2 / 42 (4.76%)	0 / 42 (0.00%)	2 / 39 (5.13%)
occurrences (all)	2	0	2
Nausea			
subjects affected / exposed	3 / 42 (7.14%)	3 / 42 (7.14%)	0 / 39 (0.00%)
occurrences (all)	3	3	0
Toothache			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	1 / 39 (2.56%)
occurrences (all)	0	1	1
Abdominal pain			
subjects affected / exposed	2 / 42 (4.76%)	0 / 42 (0.00%)	0 / 39 (0.00%)
occurrences (all)	2	0	0
Haemorrhoids			
subjects affected / exposed	2 / 42 (4.76%)	0 / 42 (0.00%)	1 / 39 (2.56%)
occurrences (all)	2	0	1
Vomiting			
subjects affected / exposed	2 / 42 (4.76%)	2 / 42 (4.76%)	1 / 39 (2.56%)
occurrences (all)	2	2	1
Skin and subcutaneous tissue disorders			
Urticaria			
subjects affected / exposed	3 / 42 (7.14%)	0 / 42 (0.00%)	1 / 39 (2.56%)
occurrences (all)	3	0	1
Eczema			

subjects affected / exposed	2 / 42 (4.76%)	1 / 42 (2.38%)	3 / 39 (7.69%)
occurrences (all)	2	1	3
Rash			
subjects affected / exposed	0 / 42 (0.00%)	2 / 42 (4.76%)	2 / 39 (5.13%)
occurrences (all)	0	2	4
Pruritus			
subjects affected / exposed	1 / 42 (2.38%)	1 / 42 (2.38%)	0 / 39 (0.00%)
occurrences (all)	1	1	0
Renal and urinary disorders			
Leukocyturia			
subjects affected / exposed	2 / 42 (4.76%)	3 / 42 (7.14%)	0 / 39 (0.00%)
occurrences (all)	2	3	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	4 / 42 (9.52%)	0 / 42 (0.00%)	3 / 39 (7.69%)
occurrences (all)	4	0	3
Back pain			
subjects affected / exposed	4 / 42 (9.52%)	5 / 42 (11.90%)	1 / 39 (2.56%)
occurrences (all)	4	9	1
Myalgia			
subjects affected / exposed	1 / 42 (2.38%)	1 / 42 (2.38%)	2 / 39 (5.13%)
occurrences (all)	5	1	2
Pain in extremity			
subjects affected / exposed	1 / 42 (2.38%)	3 / 42 (7.14%)	2 / 39 (5.13%)
occurrences (all)	1	3	2
Muscle spasms			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	2
Infections and infestations			
Cystitis			
subjects affected / exposed	4 / 42 (9.52%)	4 / 42 (9.52%)	2 / 39 (5.13%)
occurrences (all)	5	6	3
Influenza			
subjects affected / exposed	0 / 42 (0.00%)	4 / 42 (9.52%)	1 / 39 (2.56%)
occurrences (all)	0	5	1
Nasopharyngitis			

subjects affected / exposed	10 / 42 (23.81%)	7 / 42 (16.67%)	7 / 39 (17.95%)
occurrences (all)	22	13	15
Oral herpes			
subjects affected / exposed	2 / 42 (4.76%)	3 / 42 (7.14%)	3 / 39 (7.69%)
occurrences (all)	6	19	3
Pharyngitis			
subjects affected / exposed	4 / 42 (9.52%)	3 / 42 (7.14%)	1 / 39 (2.56%)
occurrences (all)	6	10	1
Rhinitis			
subjects affected / exposed	3 / 42 (7.14%)	0 / 42 (0.00%)	1 / 39 (2.56%)
occurrences (all)	5	0	1
Sinusitis			
subjects affected / exposed	3 / 42 (7.14%)	0 / 42 (0.00%)	2 / 39 (5.13%)
occurrences (all)	4	0	2
Upper respiratory tract infection			
subjects affected / exposed	10 / 42 (23.81%)	6 / 42 (14.29%)	8 / 39 (20.51%)
occurrences (all)	26	12	36
Urinary tract infection			
subjects affected / exposed	6 / 42 (14.29%)	7 / 42 (16.67%)	5 / 39 (12.82%)
occurrences (all)	8	7	23
Conjunctivitis			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	2 / 39 (5.13%)
occurrences (all)	1	0	2
Hordeolum			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Otitis externa			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Periodontitis			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	1 / 39 (2.56%)
occurrences (all)	1	0	1
Bronchitis			
subjects affected / exposed	2 / 42 (4.76%)	1 / 42 (2.38%)	2 / 39 (5.13%)
occurrences (all)	5	1	2
Ear infection			

subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis			
subjects affected / exposed	1 / 42 (2.38%)	1 / 42 (2.38%)	0 / 39 (0.00%)
occurrences (all)	2	1	0
Laryngitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	3
Localised infection			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	1 / 39 (2.56%)
occurrences (all)	1	0	1
Varicella zoster virus infection			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Dyslipidaemia			
subjects affected / exposed	1 / 42 (2.38%)	1 / 42 (2.38%)	2 / 39 (5.13%)
occurrences (all)	1	1	2
Hypercholesterolaemia			
subjects affected / exposed	4 / 42 (9.52%)	5 / 42 (11.90%)	2 / 39 (5.13%)
occurrences (all)	10	5	4

Non-serious adverse events	Satralizumab Open-Label Period	Placebo + Baseline Treatment Open Label Period	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	30 / 32 (93.75%)	
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 1 (0.00%)	3 / 32 (9.38%)	
occurrences (all)	0	3	
Hypertension			
subjects affected / exposed	0 / 1 (0.00%)	1 / 32 (3.13%)	
occurrences (all)	0	2	
Hypotension			

subjects affected / exposed	1 / 1 (100.00%)	2 / 32 (6.25%)	
occurrences (all)	1	2	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 1 (0.00%)	4 / 32 (12.50%)	
occurrences (all)	0	5	
Pyrexia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 32 (3.13%)	
occurrences (all)	0	1	
Non-cardiac chest pain			
subjects affected / exposed	0 / 1 (0.00%)	3 / 32 (9.38%)	
occurrences (all)	0	5	
Immune system disorders			
Hypocomplementaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences (all)	0	0	
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	1 / 1 (100.00%)	0 / 32 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 1 (0.00%)	3 / 32 (9.38%)	
occurrences (all)	0	3	
Oropharyngeal pain			
subjects affected / exposed	1 / 1 (100.00%)	2 / 32 (6.25%)	
occurrences (all)	1	2	
Rhinorrhoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 1 (0.00%)	2 / 32 (6.25%)	
occurrences (all)	0	2	
Insomnia			

subjects affected / exposed	0 / 1 (0.00%)	3 / 32 (9.38%)	
occurrences (all)	0	3	
Depression			
subjects affected / exposed	0 / 1 (0.00%)	2 / 32 (6.25%)	
occurrences (all)	0	2	
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences (all)	0	0	
Lymphocyte count decreased			
subjects affected / exposed	0 / 1 (0.00%)	3 / 32 (9.38%)	
occurrences (all)	0	3	
Alanine aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 32 (3.13%)	
occurrences (all)	0	2	
Blood fibrinogen decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences (all)	0	0	
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 32 (3.13%)	
occurrences (all)	0	1	
Blood fibrinogen increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences (all)	0	0	
Blood pressure increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences (all)	0	0	
Neutrophil count decreased			
subjects affected / exposed	1 / 1 (100.00%)	2 / 32 (6.25%)	
occurrences (all)	1	6	
Prothrombin time prolonged			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences (all)	0	0	
White blood cell count decreased			

subjects affected / exposed	1 / 1 (100.00%)	2 / 32 (6.25%)	
occurrences (all)	1	5	
Blood cholesterol increased			
subjects affected / exposed	0 / 1 (0.00%)	2 / 32 (6.25%)	
occurrences (all)	0	2	
Haemoglobin decreased			
subjects affected / exposed	1 / 1 (100.00%)	0 / 32 (0.00%)	
occurrences (all)	1	0	
Lymphocyte percentage decreased			
subjects affected / exposed	1 / 1 (100.00%)	0 / 32 (0.00%)	
occurrences (all)	1	0	
Lymphocyte percentage increased			
subjects affected / exposed	1 / 1 (100.00%)	0 / 32 (0.00%)	
occurrences (all)	1	0	
Monocyte count increased			
subjects affected / exposed	1 / 1 (100.00%)	0 / 32 (0.00%)	
occurrences (all)	1	0	
Neutrophil count increased			
subjects affected / exposed	1 / 1 (100.00%)	0 / 32 (0.00%)	
occurrences (all)	1	0	
Neutrophil percentage increased			
subjects affected / exposed	1 / 1 (100.00%)	0 / 32 (0.00%)	
occurrences (all)	1	0	
Platelet count increased			
subjects affected / exposed	1 / 1 (100.00%)	0 / 32 (0.00%)	
occurrences (all)	1	0	
White blood cell count increased			
subjects affected / exposed	1 / 1 (100.00%)	0 / 32 (0.00%)	
occurrences (all)	1	0	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 1 (0.00%)	1 / 32 (3.13%)	
occurrences (all)	0	2	
Ligament sprain			

subjects affected / exposed	0 / 1 (0.00%)	5 / 32 (15.63%)	
occurrences (all)	0	5	
Thermal burn			
subjects affected / exposed	0 / 1 (0.00%)	1 / 32 (3.13%)	
occurrences (all)	0	1	
Rib fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 1 (0.00%)	2 / 32 (6.25%)	
occurrences (all)	0	2	
Headache			
subjects affected / exposed	1 / 1 (100.00%)	5 / 32 (15.63%)	
occurrences (all)	1	8	
Hypoaesthesia			
subjects affected / exposed	0 / 1 (0.00%)	3 / 32 (9.38%)	
occurrences (all)	0	6	
Paraesthesia			
subjects affected / exposed	0 / 1 (0.00%)	2 / 32 (6.25%)	
occurrences (all)	0	2	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 1 (0.00%)	2 / 32 (6.25%)	
occurrences (all)	0	2	
Iron deficiency anaemia			
subjects affected / exposed	0 / 1 (0.00%)	4 / 32 (12.50%)	
occurrences (all)	0	4	
Leukopenia			
subjects affected / exposed	0 / 1 (0.00%)	5 / 32 (15.63%)	
occurrences (all)	0	6	
Lymphopenia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 32 (3.13%)	
occurrences (all)	0	1	
Neutropenia			

subjects affected / exposed	0 / 1 (0.00%)	1 / 32 (3.13%)	
occurrences (all)	0	1	
Ear and labyrinth disorders			
Ear discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	2 / 32 (6.25%)	
occurrences (all)	0	4	
Blepharitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 1 (0.00%)	2 / 32 (6.25%)	
occurrences (all)	0	2	
Constipation			
subjects affected / exposed	0 / 1 (0.00%)	2 / 32 (6.25%)	
occurrences (all)	0	4	
Dental caries			
subjects affected / exposed	0 / 1 (0.00%)	5 / 32 (15.63%)	
occurrences (all)	0	5	
Diarrhoea			
subjects affected / exposed	1 / 1 (100.00%)	5 / 32 (15.63%)	
occurrences (all)	2	5	
Gastritis			
subjects affected / exposed	0 / 1 (0.00%)	2 / 32 (6.25%)	
occurrences (all)	0	3	
Nausea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences (all)	0	0	
Toothache			
subjects affected / exposed	0 / 1 (0.00%)	4 / 32 (12.50%)	
occurrences (all)	0	5	
Abdominal pain			

subjects affected / exposed	1 / 1 (100.00%)	2 / 32 (6.25%)	
occurrences (all)	1	2	
Haemorrhoids			
subjects affected / exposed	1 / 1 (100.00%)	0 / 32 (0.00%)	
occurrences (all)	1	0	
Vomiting			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Urticaria			
subjects affected / exposed	0 / 1 (0.00%)	2 / 32 (6.25%)	
occurrences (all)	0	3	
Eczema			
subjects affected / exposed	0 / 1 (0.00%)	2 / 32 (6.25%)	
occurrences (all)	0	2	
Rash			
subjects affected / exposed	1 / 1 (100.00%)	1 / 32 (3.13%)	
occurrences (all)	1	1	
Pruritus			
subjects affected / exposed	1 / 1 (100.00%)	1 / 32 (3.13%)	
occurrences (all)	1	1	
Renal and urinary disorders			
Leukocyturia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 32 (3.13%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 1 (0.00%)	2 / 32 (6.25%)	
occurrences (all)	0	2	
Back pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 32 (3.13%)	
occurrences (all)	0	1	
Myalgia			
subjects affected / exposed	0 / 1 (0.00%)	3 / 32 (9.38%)	
occurrences (all)	0	3	
Pain in extremity			

subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences (all)	0	0	
Muscle spasms			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Cystitis			
subjects affected / exposed	0 / 1 (0.00%)	3 / 32 (9.38%)	
occurrences (all)	0	3	
Influenza			
subjects affected / exposed	0 / 1 (0.00%)	4 / 32 (12.50%)	
occurrences (all)	0	5	
Nasopharyngitis			
subjects affected / exposed	0 / 1 (0.00%)	11 / 32 (34.38%)	
occurrences (all)	0	49	
Oral herpes			
subjects affected / exposed	0 / 1 (0.00%)	4 / 32 (12.50%)	
occurrences (all)	0	42	
Pharyngitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 32 (0.00%)	
occurrences (all)	0	0	
Rhinitis			
subjects affected / exposed	1 / 1 (100.00%)	0 / 32 (0.00%)	
occurrences (all)	1	0	
Sinusitis			
subjects affected / exposed	0 / 1 (0.00%)	3 / 32 (9.38%)	
occurrences (all)	0	3	
Upper respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	8 / 32 (25.00%)	
occurrences (all)	0	10	
Urinary tract infection			
subjects affected / exposed	0 / 1 (0.00%)	6 / 32 (18.75%)	
occurrences (all)	0	16	
Conjunctivitis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 32 (3.13%)	
occurrences (all)	0	1	

Hordeolum			
subjects affected / exposed	0 / 1 (0.00%)	2 / 32 (6.25%)	
occurrences (all)	0	2	
Otitis externa			
subjects affected / exposed	0 / 1 (0.00%)	2 / 32 (6.25%)	
occurrences (all)	0	2	
Periodontitis			
subjects affected / exposed	0 / 1 (0.00%)	3 / 32 (9.38%)	
occurrences (all)	0	6	
Bronchitis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 32 (3.13%)	
occurrences (all)	0	1	
Ear infection			
subjects affected / exposed	1 / 1 (100.00%)	1 / 32 (3.13%)	
occurrences (all)	2	1	
Gastroenteritis			
subjects affected / exposed	0 / 1 (0.00%)	2 / 32 (6.25%)	
occurrences (all)	0	8	
Laryngitis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 32 (3.13%)	
occurrences (all)	0	1	
Localised infection			
subjects affected / exposed	1 / 1 (100.00%)	0 / 32 (0.00%)	
occurrences (all)	1	0	
Tonsillitis			
subjects affected / exposed	1 / 1 (100.00%)	1 / 32 (3.13%)	
occurrences (all)	1	1	
Varicella zoster virus infection			
subjects affected / exposed	0 / 1 (0.00%)	2 / 32 (6.25%)	
occurrences (all)	0	2	
Metabolism and nutrition disorders			
Dyslipidaemia			
subjects affected / exposed	0 / 1 (0.00%)	2 / 32 (6.25%)	
occurrences (all)	0	2	
Hypercholesterolaemia			

subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	2 / 32 (6.25%) 2	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
29 November 2013	Definition of NMOSD was changed. The population was limited to optic neuritis or transverse myelitis with seropositivity in anti-AQP4 antibody. Adolescent subjects aged 1217 years were allowed to enter the study. Considering the impact of previous treatment on safety and efficacy, the treatment prohibited duration was modified. Methods and duration of contraception were added to exclusion criteria. Because patients with NMO/NMOSD tend to show lower white blood cell value due to baseline treatment with immunosuppressant drugs, the white blood cell exclusion criterion was modified. The protocol v2 was released prior to any patients being enrolled in the study.
27 February 2014	Suicidality assessment (C-SSRS) was added as a safety objective per Food and Drug Administration (FDA) request. Based on epidemiologic data, the percentage of patients with negative anti-AQP4 serostatus at screening was capped at 30% in order to reflect the real world population. Further clarifications on the process of screening for potential clinical relapses were added. The roles and responsibilities of the treating and assessing investigator were introduced and the blinding of study and site personnel to certain laboratory parameters were clarified.
18 December 2014	The criteria for protocol-defined relapse (PDR) were aligned with another pivotal Phase III study in patients with NMO/NMOSD (study BN40900 / SA309JG/ EudraCT ID 2015-005431-41), which was modified based on FDA's comment. According to the Paediatric Committee's (PDCO's) request at least 8 adolescents were to be enrolled. Combination baseline treatment for adolescents was allowed given the low prevalence of pediatric patients and their treatment situation. Additional follow up assessments for adolescents were added. A blood sample collected before screening was accepted for anti-AQP4 antibody screening assessment in case the blood sample at screening was negative for anti-AQP4 antibody, considering the possibility that anti-AQP4 antibody status may change from positive to negative due to treatment for relapse. Permitted relapse treatments and prohibited treatments were modified considering clinical practice. Time limit of relapse evaluation to be recognized as PDR was aligned to another pivotal Phase III study in participants with NMO/NMOSD (study BN40900/SA-309JG// EudraCT ID 2015-005431-41) to avoid incomplete or biased reporting, and relapse assessment procedures were clarified. To avoid missing potential relapses, additional phone calls between visits and instructions to remind participants of possible relapse symptoms were added. The conditions when a participant could move from the double blind (DB) period to the open-label extension (OLE) period were clarified.
03 June 2015	Considering the clinical situation where no drugs have been approved for treatment of NMO and NMOSD, the open-label extension period was extended from an ethical point of view. This change was also in alignment with the agreed pediatric investigation plan (PIP). Inclusion of adolescents with negative anti-AQP4 serostatus at screening was allowed.
19 October 2015	Clarification that the population which was capped by anti-AQP4 antibody status at screening was limited only to adults.
14 December 2016	Addition that adolescents may be enrolled into the OLE period after the total number of PDRs confirmed by the clinical endpoint committee (CEC) reached 26. The minimum number of adolescents (12 to 17 years old) with positive anti-AQP4 serostatus at screening was changed from 6 to 4. The use of satralizumab prefilled syringe (PFS) with needle safety device (NSD) were implemented to be used in the OLE period after the total number of CEC confirmed PDRs reached 26.

17 April 2017	The description on the timing of satralizumab PFS with NSD implementation was modified so that satralizumab PFS with NSD could be administered for participants who had already entered into open-label extension period after availability at each study site. The reporting procedure when the medical device (satralizumab PFS with NSD) resulted in an adverse event (AE) to an individual other than the study participant was clarified.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported