Clinical trial results:
A Multicenter, Single Arm, Open-label Study to Evaluate the Long-term Safety and Efficacy of Satralizumab in Patients with Neuromyelitis Optica Spectrum Disorder (NMOSD)

Summary

EudraCT number	2020-003413-35
Trial protocol	GB DE HU BG PL IT HR
Global end of trial date	28 May 2024

Results information

Result version number	v1 (current)
This version publication date	14 December 2024
First version publication date	14 December 2024

Trial information

Trial identification

Sponsor protocol code	WN42349

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04660539
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	F. Hoffmann-La Roche AG
Sponsor organisation address	Grenzacherstrasse 124, Basel, Switzerland, CH-4058
Public contact	F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, +41 616878333, global.trial_information@roche.com
Scientific contact	F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, +41 616878333, global.trial_information@roche.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	28 May 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	28 May 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The study aims to evaluate the long-term safety and efficacy of satralizumab in participants with neuromyelitis optic spectrum disorder (NMOSD). Study WN42349 is not a part of a PIP. However, the parent studies (2013-003752-21 and 2015-005431-41) were a part of a PIP, with an EMA-PIP number of EMEA-001625-PIP01-14.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 March 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Bulgaria: 4
Country: Number of subjects enrolled	Canada: 10
Country: Number of subjects enrolled	Germany: 3
Country: Number of subjects enrolled	Spain: 3
Country: Number of subjects enrolled	France: 1
Country: Number of subjects enrolled	United Kingdom: 2
Country: Number of subjects enrolled	Georgia: 1
Country: Number of subjects enrolled	Croatia: 1
Country: Number of subjects enrolled	Hungary: 2
Country: Number of subjects enrolled	Italy: 6
Country: Number of subjects enrolled	Japan: 20
Country: Number of subjects enrolled	Korea, Republic of: 5
Country: Number of subjects enrolled	Malaysia: 1
Country: Number of subjects enrolled	Poland: 30
Country: Number of subjects enrolled	Romania: 1
Country: Number of subjects enrolled	Türkiye: 1
Country: Number of subjects enrolled	Taiwan: 16
Country: Number of subjects enrolled	Ukraine: 12
Country: Number of subjects enrolled	United States: 47

Worldwide total number of subjects	166
EEA total number of subjects	51

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)	8
Adults (18-64 years)	154
From 65 to 84 years	4
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 119 participants from studies BN40898 & BN40900 rolled over in study WN42349 at 53 sites in 17 countries. 'All Participants-treated population' is used to report results, which includes 166 participants who received at least one dose of satralizumab at any time during parent studies or this study, irrespective of enrollment in WN42349.

Pre-assignment

Screening details:

Participants from 2013-003752-21 and 2015-005431-41 enrolled in this study to receive satralizumab treatment. Participants were permitted to use azathioprine (AZA) or mycophenolate mofetil (MMF) or oral corticosteroids during the study as background immunosuppressive treatments.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Satralizumab

Arm description:

Participants rolled over from studies 2013-003752-21 and 2015-005431-41 received satralizumab, 120 milligrams (mg) as subcutaneous (SC) injection, every 4 weeks (Q4W) up to a maximum duration of 3 years in the current study. Participants who received at least 1 dose of satralizumab at any time during parent studies or this study, irrespective of enrollment in the current study are represented here.

Arm type	Experimental
Investigational medicinal product name	Satralizumab
Investigational medicinal product code	RO5541267
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Satralizumab, 120 mg, as SC injection for up to 3 years.

Number of subjects in period 1	Satralizumab
Started	166
Completed	106
Not completed	60
Consent withdrawn by subject	21
Adverse Event	10
Switch To Commercial Satralizumab	1
Non-Compliance With Study Drug	3
Pregnancy	2
Lost to follow-up	5
Reason not Specified	12

Lack of efficacy	4
Protocol deviation	2

Baseline characteristics

Reporting groups	
Reporting group title	Satralizumab

Reporting group description:

Participants rolled over from studies 2013-003752-21 and 2015-005431-41 received satralizumab, 120 milligrams (mg) as subcutaneous (SC) injection, every 4 weeks (Q4W) up to a maximum duration of 3 years in the current study. Participants who received at least 1 dose of satralizumab at any time during parent studies or this study, irrespective of enrollment in the current study are represented here.

Reporting group values	Satralizumab	Total	
Number of subjects	166	166	
Age categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	42.7		
standard deviation	± 13.3	-	
Sex: Female, Male Units: participants			
Female	142	142	
Male	24	24	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	12	12	
Not Hispanic or Latino	147	147	
Unknown or Not Reported	7	7	
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	2	2	
Asian	47	47	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	17	17	
White	95	95	
More than one race	0	0	
Other	5	5	

End points

End points reporting groups

Reporting group title	Satralizumab

Reporting group description:

Participants rolled over from studies 2013-003752-21 and 2015-005431-41 received satralizumab, 120 milligrams (mg) as subcutaneous (SC) injection, every 4 weeks (Q4W) up to a maximum duration of 3 years in the current study. Participants who received at least 1 dose of satralizumab at any time during parent studies or this study, irrespective of enrollment in the current study are represented here.

Primary: Number of Participants with Adverse Events (AEs) and Serious Adverse Events (SAEs)

End point title	Number of Participants with Adverse Events (AEs) and Serious Adverse Events (SAEs)[1]

End point description:

AE=any untoward medical occurrence in a participant administered a medicinal product, regardless of causal relationship with it. AE=unfavorable & unintended sign, symptoms/disease temporally associated with use of medicinal product, whether or not considered related to it. SAE=any significant hazard, contraindication/side effect that is fatal/ life-threatening, requires hospitalization/prolongation of existing hospitalization, results in persistent/significant disability/incapacity, is congenital anomaly, is medically significant/requires intervention. First dosing visit in current study/randomization visit in the parent studies was considered as baseline. All AEs from time of randomization in parent studies up to end of study WN42349 for satralizumab-treated participants are reported here. All Participants-treated population=participants who received at least 1 dose of satralizumab at any time during parent or this study, irrespective of enrollment in current study.

End point type	Primary

End point timeframe:

Baseline up to 523 weeks

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistics was planned for this endpoint.

End point values	Satralizumab			
Subject group type	Reporting group			
Number of subjects analysed	166			
Units: participants				
AEs	162			
SAEs	44			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Adverse Events of Special Interest (AESIs) and Selected AEs

End point title	Number of Participants with Adverse Events of Special Interest (AESIs) and Selected AEs[2]

End point description:

An AESIs included potential drug induced liver injury & suspected transmission of infectious agent by

study drug defined as any organism, virus or infectious particle, pathogenic or non-pathogenic causing clinical symptoms or laboratory findings that indicate infection in participant exposed to medicinal product. Selected AEs included infections that required treatments with IV antibiotics, antifungals or antivirals; opportunistic infections that required treatment with oral antibiotics, antifungals or antivirals and injection related reaction. First dosing visit in current study or randomization visit in parent studies (2013-003752-21/2015-005431-41) was considered as baseline for this endpoint. All AEs from time of randomization in parent studies up to end of study WN42349 for satralizumab-treated participants are reported here. All Participants-treated population included participants who received at least 1 dose of satralizumab at any time during parent or this study.

End point type	Primary

End point timeframe:

Baseline up to 523 weeks

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistics was planned for this endpoint.

End point values	Satralizumab			
Subject group type	Reporting group			
Number of subjects analysed	166			
Units: participants				
AESIs	0			
Selected AEs	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Suicidality Assessed Using Columbia-Suicide Severity Rating Scale (C-SSRS)

End point title	Number of Participants with Suicidality Assessed Using Columbia-Suicide Severity Rating Scale (C-SSRS)

End point description:

C-SSRS=assessment tool used to assess lifetime suicidality of a participant (at baseline) and any new instances of suicidality (since last visit). Structured interview prompts recollection of suicidal ideation, including intensity of ideation, behavior and attempts with actual/potential lethality. Categories have 2 responses(yes/no) & include a-Wish to be Dead; b-Non-specific Active Suicidal Thoughts; c-Active Suicidal Ideation with Any Methods(Not Plan) w/o Intent to Act; d-Active Suicidal Ideation with Some Intent to Act, w/o Specific Plan; e-Active Suicidal Ideation with Specific Plan & Intent, f-Preparatory Acts & Behavior; g-Aborted Attempt; h-Interrupted Attempt; i-Actual Attempt(non-fatal); j-Completed Suicide. Suicidal ideation or behavior is indicated by yes answer to any categories. Score=0 if no suicide risk present. Score≥1=suicidal ideation or behavior. All Participants-treated population. Baseline=1st dosing visit in current study/randomization visit in parent studies.

End point type	Secondary

End point timeframe:

Baseline up to 523 weeks

End point values	Satralizumab			
Subject group type	Reporting group			
Number of subjects analysed	166			
Units: participants				
a- Baseline	7			
a- Post-baseline	5			
b- Baseline	5			
b- Post-baseline	2			
c- Baseline	1			
c- Post-baseline	0			
d- Baseline	1			
d- Post-baseline	0			
e- Baseline (n=166)	1			
e- Post-baseline	0			
f- Baseline	2			
f- Post-baseline	0			
i- Baseline	3			
i- Post-baseline	1			
j- Baseline	0			
j- Post-baseline	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Serious Infections and Hepatotoxicity

End point title	Number of Participants with Serious Infections and Hepatotoxicity

End point description:

Hepatotoxicity was defined using the following Medical Dictionary for Regulatory Activities Standardised MedDRA Queries (MedDRA SMQs) - Cholestasis and jaundice of hepatic origin (SMQ narrow) and Drug related hepatic disorders - severe events only (SMQ narrow). The first dosing visit in the current study or randomization visit in the parent studies (2013-003752-21/2015-005431-41) was considered as baseline for this endpoint. Data for all serious infections and hepatotoxicity from time of randomization in parent studies up to end of study WN42349 for satralizumab-treated participants are reported here. All Participants-treated population=participants who received at least 1 dose of satralizumab at any time during parent or this study, irrespective of enrollment in WN42349 .

End point type	Secondary

End point timeframe:

Baseline up to 523 weeks

End point values	Satralizumab			
Subject group type	Reporting group			
Number of subjects analysed	166			
Units: participants				
Serious Infections	19			
Hepatotoxicity	8			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Relapse-Free Participants

End point title	Percentage of Relapse-Free Participants

End point description:

Protocol-defined relapse was the occurrence of new or worsening neurological symptoms attributable to NMOSD. New or worsening neurological symptoms that occur < 31 days following the onset of a PDR were considered part of the same relapse. The first dosing visit in the current study or randomization visit in the parent studies (2013-003752-21/2015-005431-41) was considered as baseline for this endpoint. All data from the time of randomization in the parent studies up to end of study WN42349 for satralizumab-treated participants are reported here. Participants who did not experience any relapse events are reported here. Percentages have been rounded off to the nearest decimal point. All Participants-treated population included participants who received at least one dose of satralizumab at any time either during the parent studies or this study, irrespective of enrollment in current study.

End point type	Secondary

End point timeframe:

Baseline up to 528 weeks

End point values	Satralizumab			
Subject group type	Reporting group			
Number of subjects analysed	166			
Units: percentage of participants				
number (not applicable)	70.5			

Statistical analyses

No statistical analyses for this end point

Secondary: Time to First Protocol-defined Relapse (PDR) as Assessed by Investigator (iPDR)

End point title	Time to First Protocol-defined Relapse (PDR) as Assessed by Investigator (iPDR)

End point description:

Time to first relapse (TFR) was defined as the time from randomization in parent studies to the first occurrence of the first iPDR. PDR=occurrence of new or worsening neurological symptoms attributable to NMO/NMOSD. New/worsening neurological symptoms occurring < 31 days following onset of PDR were considered part of same relapse. Time point of relapse onset=time at which participant experienced new/worsening neurological symptoms representing NMOSD clinical relapse(s). For participants who did not relapse at the time of analysis, TFR was censored at clinical cutoff date (CCOD) or at withdrawal from study. Baseline=1st visit in current study/randomization visit in parent studies. TFR data from time of randomization in parent studies to end of this study for satralizumab-treated participants are reported. All Participants-treated population. 99999=insufficient number of events to estimate median

and 95% CI.

End point type	Secondary

End point timeframe:

Baseline up to 528 weeks

End point values	Satralizumab			
Subject group type	Reporting group			
Number of subjects analysed	166			
Units: weeks				
median (confidence interval 95%)	99999 (99999 to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: iPDR-free Rate up to Week 456

End point title	iPDR-free Rate up to Week 456

End point description:

iPDR free rate was defined as percentage of participants who did not experience a protocol-defined relapse as assessed by the investigator. PDR was the occurrence of new or worsening neurological symptoms attributable to NMOSD. New or worsening neurological symptoms that occur <31 days following the onset of a PDR were considered part of the same relapse. First dosing visit in the current study or randomization visit in parent studies (2013-003752-21/2015-005431-41) was considered as baseline for this endpoint. All data from the time of randomization in the parent studies up to Week 456 for satralizumab-treated participants are reported here. Percentages have been rounded off to the nearest decimal point. Kaplan-Meier method was used to estimate the iPDR-free rates. All Participants-treated population included participants who received at least one dose of satralizumab at any time either during the parent studies or this study, irrespective of enrollment in current study.

End point type	Secondary

End point timeframe:

Baseline up to Week 456

End point values	Satralizumab			
Subject group type	Reporting group			
Number of subjects analysed	166			
Units: percentage of participants				
number (confidence interval 95%)	67.11 (58.61 to 74.25)			

Statistical analyses

No statistical analyses for this end point

Secondary: Annualized Relapse Rate (ARR)

End point title	Annualized Relapse Rate (ARR)

End point description:

ARR calculated as total number of relapses experienced divided by participant-years of whole study period. Adjusted AAR was calculated using Poisson regression model adjusted by study identifier (BN40898, BN40900). ARR was assessed from randomization in parent studies to 1st occurrence of iPDR. PDR = occurrence of new/worsening neurological symptoms attributable to NMO/NMOSD. New/worsening neurological symptoms occurring < 31 days following onset of PDR were considered part of same relapse. Time point of relapse onset=time at which participant experienced any new/worsening neurological symptoms representing NMOSD clinical relapse(s). Baseline was defined as first dosing visit in current study/randomization visit in parent studies (2013-003752-21/2015-005431-41). All ARR data from time of randomization in parent studies up to end of study WN42349 for satralizumab-treated participants are reported here. All Participants-treated population included participants is used for analysis.

End point type	Secondary

End point timeframe:

Baseline up to 528 weeks

End point values	Satralizumab			
Subject group type	Reporting group			
Number of subjects analysed	166			
Units: relapses per participant-year				
number (confidence interval 95%)	0.0788 (0.0633 to 0.0982)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Expanded Disability Status Scale (EDSS) Score

End point title	Change in Expanded Disability Status Scale (EDSS) Score

End point description:

EDSS=quantitative measure of disability and for assessment of severity of relapse for participants with NMOSD. Values from 0 points (normal neurological examination) to 10 points (death), increasing in increments of 0.5 points. Higher scores represent increased disability. Baseline=last observation on/before the day of first study drug administration in this study/parent studies (2013-003752-21/2015-005431-41). EDSS data from the time of randomization in parent studies to end of this study for satralizumab-treated participants are reported. All Participants-treated population included participants who received at least one dose of satralizumab at any time either during the parent studies or this study, irrespective of enrollment in the current study. Number analyzed=number of participants with data available for analysis. "n"= participants with data available for analysis at the specified timepoint. 99999=standard deviation (SD) was not evaluable as only 1 participant was analyzed.

End point type	Secondary

End point timeframe:

Baseline and every 24 weeks (up to 528 weeks)

End point values	Satralizumab			
Subject group type	Reporting group			
Number of subjects analysed	165			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (n=165)	3.80 (± 1.57)			
Change from Baseline at Week 24 (n=162)	-0.08 (± 0.77)			
Change from Baseline at Week 48 (n=151)	-0.16 (± 0.72)			
Change from Baseline at Week 72 (n=147)	-0.14 (± 0.80)			
Change from Baseline at Week 96 (n=141)	-0.18 (± 0.86)			
Change from Baseline at Week 120 (n=135)	-0.14 (± 0.90)			
Change from Baseline at Week 144 (n=133)	-0.09 (± 0.97)			
Change from Baseline at Week 168 (n=128)	-0.16 (± 0.90)			
Change from Baseline at Week 192 (n=129)	-0.13 (± 0.95)			
Change from Baseline at Week 216 (n=124)	-0.22 (± 0.99)			
Change from Baseline at Week 240 (n=116)	-0.21 (± 0.95)			
Change from Baseline at Week 264 (n=114)	-0.25 (± 0.92)			
Change from Baseline at Week 288 (n=106)	-0.34 (± 0.99)			
Change from Baseline at Week 312 (n=97)	-0.44 (± 1.02)			
Change from Baseline at Week 336 (n=87)	-0.42 (± 1.15)			
Change from Baseline at Week 360 (n=82)	-0.51 (± 1.24)			
Change from Baseline at Week 384 (n=66)	-0.37 (± 1.22)			
Change from Baseline at Week 408 (n=52)	-0.26 (± 1.20)			
Change from Baseline at Week 432 (n=48)	-0.31 (± 1.16)			
Change from Baseline at Week 456 (n=37)	-0.31 (± 1.23)			
Change from Baseline at Week 480 (n=16)	0.00 (± 1.03)			
Change from Baseline at Week 504 (n=1)	0.00 (± 99999)			
Change from Baseline at Week 528 (n=1)	-0.50 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Time to First EDSS Scores Worsening

End point title	Time to First EDSS Scores Worsening

End point description:

EDSS=quantitative measure with values from 0 points (normal neurological examination) to 10 points (death), increasing in increments of 0.5 points. EDSS worsening=(a) worsening of ≥2 points in EDSS score for participants with a baseline score (BS) of 0, (b) worsening of ≥1points in EDSS score for participants with a BS of 1-5, or (c) worsening of ≥0.5 points in EDSS score for participants with a BS of ≥5.5. Participants were censored at date of last EDSS assessment/if no assessment was performed at randomization. Baseline is the last observation on/before day of 1st drug administration in this study/parent studies (2013-003752-21/2015-005431-41). EDSS data from randomization in parent studies to end of this study for satralizumab-treated participants are reported. All Participants-treated population is used. Number analyzed=participants with data available for analysis. 99999=there was an insufficient number of events to estimate median & 95% CI.

End point type	Secondary

End point timeframe:

Baseline up to 528 weeks

End point values	Satralizumab			
Subject group type	Reporting group			
Number of subjects analysed	165			
Units: weeks				
median (confidence interval 95%)	99999 (99999 to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Visual Acuity (VA) Assessed by a Snellen 20-Foot Wall Chart

End point title	Change in Visual Acuity (VA) Assessed by a Snellen 20-Foot Wall Chart

End point description:

VA was measured using Snellen 20-foot wall chart & then converted to logMAR VA scoring. Lower values indicate better visual acuity. Data are reported for right eye (OD) & left eye (OS). Scores worse than 20/200 [i.e. CF (counting fingers), HM (hand movement), LP (light perception), or NLP (no LP)] are converted to logMAR 1.85, logMAR 2.00, logMAR 2.70 & logMAR 3.00. LogMAR >= 1 is equivalent to Physically blind. Negative change from baseline =improvement. Baseline=first dosing visit in current study/randomization visit in parent studies. VA data from time of randomization in parent studies to end of study WN42349 for satralizumab-treated participants are reported. All Participants-treated population=participants who received at least one dose of satralizumab any time during the parent studies or this study, irrespective of enrollment in WN42349. "n"=participants with data available for analysis at specified timepoint. 99999=SD was not evaluable as only 1 participant was analyzed.

End point type	Secondary

End point timeframe:

Baseline and every 24 weeks (up to 528 weeks)

End point values	Satralizumab			
Subject group type	Reporting group			
Number of subjects analysed	166			
Units: LogMAR units				
arithmetic mean (standard deviation)				
Baseline [OD] (n=166)	0.438 (± 0.746)			
Baseline [OS] (n=166)	0.566 (± 0.899)			
Change from Baseline at Week 24 [OD] (n=162)	0.028 (± 0.297)			
Change from Baseline at Week 24 [OS] (n=161)	0.009 (± 0.329)			
Change from Baseline at Week 48 [OD] (n=152)	0.014 (± 0.363)			
Change from Baseline at Week 48 [OS] (n=152)	0.020 (± 0.385)			
Change from Baseline at Week 72 [OD] (n=148)	-0.004 (± 0.340)			
Change from Baseline at Week 72 [OS] (n=147)	-0.017 (± 0.362)			
Change from Baseline at Week 96 [OD] (n=141)	-0.024 (± 0.375)			
Change from Baseline at Week 96 [OS] (n=141)	0.030 (± 0.317)			
Change from Baseline at Week 120 [OD] (n=136)	0.015 (± 0.404)			
Change from Baseline at Week 120 [OS] (n=135)	-0.065 (± 0.404)			
Change from Baseline at Week 144 [OD] (n=134)	-0.023 (± 0.379)			
Change from Baseline at Week 144 [OS] (n=134)	-0.054 (± 0.355)			
Change from Baseline at Week 168 [OD] (n=129)	-0.004 (± 0.338)			
Change from Baseline at Week 168 [OS] (n=128)	-0.053 (± 0.324)			
Change from Baseline at Week 192 [OD] (n=131)	0.008 (± 0.383)			
Change from Baseline at Week 192 [OS] (n=130)	-0.056 (± 0.386)			
Change from Baseline at Week 216 [OD] (n=124)	0.019 (± 0.427)			
Change from Baseline at Week 216 [OS] (n=125)	-0.069 (± 0.440)			
Change from Baseline at Week 240 [OD] (n=117)	0.007 (± 0.465)			
Change from Baseline at Week 240 [OS] (n=117)	-0.085 (± 0.490)			
Change from Baseline at Week 264 [OD] (n=118)	-0.016 (± 0.421)			
Change from Baseline at Week 264 [OS] (n=119)	-0.074 (± 0.472)			
Change from Baseline at Week 288 [OD] (n=109)	0.006 (± 0.386)			
Change from Baseline at Week 288 [OS] (n=110)	-0.085 (± 0.458)			
Change from Baseline at Week 312 [OD] (n=98)	-0.043 (± 0.420)			
Change from Baseline at Week 312 [OS] (n=99)	-0.106 (± 0.499)			

Change from Baseline at Week 336 [OD] (n=92)	-0.025 (± 0.470)			
Change from Baseline at Week 336 [OS] (n=91)	-0.112 (± 0.539)			
Change from Baseline at Week 360 [OD] (n=87)	-0.008 (± 0.400)			
Change from Baseline at Week 360 [OS] (n=86)	-0.122 (± 0.524)			
Change from Baseline at Week 384 [OD] (n=72)	0.002 (± 0.421)			
Change from Baseline at Week 384 [OS] (n=71)	-0.086 (± 0.467)			
Change from Baseline at Week 408 [OD] (n=55)	0.039 (± 0.466)			
Change from Baseline at Week 408 [OS] (n=54)	-0.071 (± 0.572)			
Change from Baseline at Week 432 [OD] (n=50)	-0.010 (± 0.427)			
Change from Baseline at Week 432 [OS] (n=49)	-0.145 (± 0.509)			
Change from Baseline at Week 456 [OD] (n=38)	0.011 (± 0.373)			
Change from Baseline at Week 456 [OS] (n=38)	-0.109 (± 0.509)			
Change from Baseline at Week 480 [OD] (n=18)	-0.106 (± 0.315)			
Change from Baseline at Week 480 [OS] (n=17)	-0.018 (± 0.185)			
Change from Baseline at Week 504 [OD] (n=2)	-0.200 (± 0.141)			
Change from Baseline at Week 504 [OS] (n=2)	-0.320 (± 0.283)			
Change from Baseline at Week 528 [OD] (n=1)	0.220 (± 99999)			
Change from Baseline at Week 528 [OS] (n=1)	0.300 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Event-free Rate for EDSS Score Worsening up to Week 456

End point title	Event-free Rate for EDSS Score Worsening up to Week 456

End point description:

Event-free rate for EDSS score worsening=percentage of participants who did not experience worsening in their EDSS score from baseline. EDSS=quantitative measure of disability & for assessment of severity of relapse for participants with NMOSD. Values from 0 points (normal neurological examination) up to 10 points (death), increasing in increments of 0.5 points. Higher scores=increased disability. Participants were censored at the date of the last EDSS assessment or if no EDSS assessment was performed at the randomization date. Baseline=last observation on/before the day of first study drug administration in current study/parent studies (2013-003752-21/2015-005431-41). All EDSS data from the time of randomization in parent studies up to Week 456 for satralizumab-treated participants are reported here. Kaplan-Meier method was used to estimate the event-free rates. All Participants-treated population is used. Number analyzed is number of participants with data available for analysis.

End point type	Secondary

End point timeframe:

Baseline up to Week 456

End point values	Satralizumab			
Subject group type	Reporting group			
Number of subjects analysed	165			
Units: percentage of participants				
number (confidence interval 95%)	57.03 (46.80 to 66.01)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants without EDSS Worsening

End point title	Percentage of Participants without EDSS Worsening

End point description:

EDSS=quantitative measure of disability & for assessment of severity of relapse for participants with NMOSD. Values from 0 points (normal neurological examination) up to 10 points (death), increasing in increments of 0.5 points. Higher scores=increased disability. EDSS worsening=(a) worsening of 2/more points in EDSS score for participants with BS of 0, (b) worsening of 1/more points in EDSS score for participants with a BS of 1-5, (c) worsening of 0.5 points/more in EDSS score for participants with a BS of 5.5/more. Baseline=last observation on/before day of first study drug administration in current study/parent studies (NCT02028884/NCT02073279). EDSS data from time of randomization in parent studies up to end of study WN42349 for all participants are reported here. All Participants-treated population.Participants from parent studies who did not enroll in the current study are also considered for efficacy analysis. Number analyzed=participants with data available for analysis.

End point type	Secondary

End point timeframe:

Baseline up to 528 weeks

End point values	Satralizumab			
Subject group type	Reporting group			
Number of subjects analysed	165			
Units: percentage of participants				
number (not applicable)	64.8			

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of Interleukin-6 (IL-6) in Blood

End point title	Concentrations of Interleukin-6 (IL-6) in Blood

End point description:

Baseline was defined as last observation collected on or before day of first study drug administration in

parent studies (2013-003752-21/2015-005431-41). All data from the time of randomization in the parent studies up to the end of study WN42349 for satralizumab-treated participants are reported here. All Participants-treated population included participants who received at least one dose of satralizumab at any time either during the parent studies or this study, irrespective of enrollment in current study. Number analyzed is the number of participants with data available for analysis. "n"=participants with data available for analysis at the specified timepoint. 99999=Geometric coefficient of variation was not evaluable as only 1 participant was analyzed.

End point type	Secondary

End point timeframe:

Baseline, every two weeks from Weeks 2 to 8; every 4 weeks from Weeks 12 to 192; every 24 weeks from Weeks 216 to 528

End point values	Satralizumab			
Subject group type	Reporting group			
Number of subjects analysed	163			
Units: picograms/millilitre (pg/mL)				
geometric mean (geometric coefficient of variation)				
Baseline (n=163)	2.07 (± 70.3)			
Week 2 (n=101)	21.27 (± 97.0)			
Week 4 (n=163)	21.90 (± 108.2)			
Week 8 (n=159)	19.35 (± 110.2)			
Week 12 (n=157)	18.84 (± 99.9)			
Week 16 (n=151)	17.53 (± 108.5)			
Week 20 (n=157)	17.16 (± 108.1)			
Week 24 (n=152)	17.77 (± 101.9)			
Week 28 (n=152)	17.08 (± 109.6)			
Week 32 (n=151)	18.32 (± 107.1)			
Week 36 (n=145)	18.29 (± 95.7)			
Week 40 (n=141)	16.21 (± 95.8)			
Week 44 (n=145)	17.59 (± 108.5)			
Week 48 (n=141)	18.59 (± 105.5)			
Week 52 (n=93)	18.55 (± 101.8)			
Week 56 (n=91)	18.78 (± 124.2)			
Week 60 (n=90)	20.56 (± 99.8)			
Week 64 (n=87)	20.04 (± 98.2)			
Week 68 (n=83)	19.70 (± 95.6)			
Week 72 (n=83)	18.48 (± 103.7)			
Week 76 (n=80)	18.05 (± 89.0)			
Week 80 (n=71)	17.93 (± 101.2)			
Week 84 (n=74)	18.44 (± 111.1)			

Week 88 (n=69)	20.33 (± 89.1)			
Week 92 (n=68)	17.12 (± 100.7)			
Week 96 (n=69)	19.72 (± 107.8)			
Week 100 (n=63)	19.73 (± 111.5)			
Week 104 (n=66)	19.34 (± 82.6)			
Week 108 (n=66)	19.74 (± 94.9)			
Week 112 (n=65)	21.39 (± 95.8)			
Week 116 (n=60)	17.98 (± 93.4)			
Week 120 (n=60)	19.26 (± 108.0)			
Week 124 (n=60)	18.41 (± 98.5)			
Week 128 (n=59)	18.17 (± 93.3)			
Week 132 (n=59)	17.83 (± 98.6)			
Week 136 (n=53)	19.22 (± 100.4)			
Week 140 (n=51)	17.62 (± 91.5)			
Week 144 (n=62)	16.54 (± 101.1)			
Week 148 (n=50)	18.95 (± 82.9)			
Week 152 (n=44)	19.71 (± 100.3)			
Week 156 (n=37)	20.84 (± 78.5)			
Week 160 (n=43)	19.91 (± 81.3)			
Week 164 (n=38)	19.76 (± 76.8)			
Week 168 (n=54)	22.33 (± 87.4)			
Week 172 (n=34)	21.94 (± 82.8)			
Week 176 (n=32)	23.31 (± 75.8)			
Week 180 (n=35)	21.28 (± 78.4)			
Week 184 (n=29)	23.23 (± 98.0)			
Week 188 (n=35)	23.52 (± 86.0)			
Week 192 (n=62)	22.25 (± 76.4)			
Week 216 (n=62)	19.41 (± 102.0)			
Week 240 (n=66)	18.22 (± 101.8)			
Week 264 (n=61)	18.56 (± 99.6)			
Week 288 (n=67)	19.17 (± 94.4)			
Week 312 (n=68)	21.70 (± 82.1)			
Week 336 (n=85)	17.71 (± 103.0)			
Week 360 (n=86)	19.40 (± 77.1)			
Week 384 (n=68)	19.68 (± 91.2)			
Week 408 (n=56)	18.94 (± 113.3)			
Week 432 (n=50)	19.29 (± 124.0)			
Week 456 (n=36)	17.90 (± 94.5)			
Week 480 (n=18)	20.89 (± 42.5)			
Week 504 (n=2)	8.40 (± 32.4)			
Week 528 (n=1)	13.50 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of Soluble IL-6 Receptor (sIL-6R) in Blood

End point title	Concentrations of Soluble IL-6 Receptor (sIL-6R) in Blood

End point description:

Baseline was defined as last observation collected on or before day of first study drug administration in parent studies (2013-003752-21/2015-005431-41). All data from the time of randomization in the parent studies up to the end of study WN42349 for satralizumab-treated participants are reported here. All Participants-treated population included participants who received at least one dose of satralizumab at any time either during the parent studies or this study, irrespective of enrollment in current study. Number analyzed is the number of participants with data available for analysis. "n"=participants with data available for analysis at the specified timepoint. 99999=Geometric coefficient of variation was not evaluable as only 1 participant was analyzed.

End point type	Secondary

End point timeframe:

Baseline, every two weeks from Weeks 2 to 8; every 4 weeks from Weeks 12 to 192; every 24 weeks from Weeks 216 to 528

End point values	Satralizumab			
Subject group type	Reporting group			
Number of subjects analysed	164			
Units: nanograms/millilitre (ng/mL)				
geometric mean (geometric coefficient of variation)				
Baseline (n=164)	32.27 (± 29.0)			
Week 2 (n=102)	404.20 (± 22.1)			
Week 4 (n=163)	536.46 (± 28.3)			
Week 8 (n=161)	566.91 (± 49.4)			
Week 12 (n=159)	568.96 (± 53.8)			
Week 16 (n=152)	561.69 (± 56.2)			
Week 20 (n=157)	543.99 (± 63.3)			
Week 24 (n=154)	556.84 (± 60.5)			
Week 28 (n=154)	547.77 (± 64.0)			
Week 32 (n=153)	574.72 (± 50.9)			
Week 36 (n=146)	552.54 (± 61.9)			

Week 40 (n=142)	556.08 (± 62.9)			
Week 44 (n=150)	569.26 (± 62.3)			
Week 48 (n=143)	575.25 (± 58.8)			
Week 52 (n=93)	555.92 (± 60.3)			
Week 56 (n=93)	523.80 (± 71.6)			
Week 60 (n=91)	549.23 (± 58.7)			
Week 64 (n=88)	550.61 (± 62.7)			
Week 68 (n=83)	581.62 (± 61.5)			
Week 72 (n=84)	540.99 (± 66.6)			
Week 76 (n=81)	519.20 (± 74.5)			
Week 80 (n=71)	535.83 (± 73.9)			
Week 84 (n=74)	533.47 (± 66.9)			
Week 88 (n=69)	523.64 (± 69.8)			
Week 92 (n=70)	515.37 (± 74.5)			
Week 96 (n=70)	526.59 (± 70.4)			
Week 100 (n=64)	534.72 (± 71.2)			
Week 104 (n=66)	583.53 (± 55.1)			
Week 108 (n=66)	578.63 (± 57.1)			
Week 112 (n=65)	594.60 (± 61.0)			
Week 116 (n=60)	571.37 (± 62.0)			
Week 120 (n=61)	615.02 (± 42.7)			
Week 124 (n=61)	590.17 (± 53.3)			
Week 128 (n=60)	559.85 (± 58.7)			
Week 132 (n=59)	580.53 (± 45.0)			
Week 136 (n=55)	607.27 (± 38.6)			
Week 140 (n=52)	592.84 (± 43.8)			
Week 144 (n=62)	571.70 (± 61.2)			
Week 148 (n=50)	610.47 (± 43.8)			
Week 152 (n=44)	565.34 (± 73.3)			
Week 156 (n=38)	667.59 (± 22.3)			
Week 160 (n=43)	652.90 (± 28.8)			

Week 164 (n=38)	636.27 (± 34.9)			
Week 168 (n=54)	662.43 (± 29.9)			
Week 172 (n=34)	643.84 (± 36.8)			
Week 176 (n=32)	670.38 (± 28.3)			
Week 180 (n=35)	655.31 (± 35.0)			
Week 184 (n=30)	684.07 (± 18.5)			
Week 188 (n=35)	666.52 (± 30.8)			
Week 192 (n=62)	611.46 (± 67.0)			
Week 216 (n=63)	592.12 (± 68.9)			
Week 240 (n=71)	587.26 (± 58.7)			
Week 264 (n=63)	570.35 (± 45.3)			
Week 288 (n=67)	572.20 (± 52.2)			
Week 312 (n=68)	608.11 (± 35.0)			
Week 336 (n=85)	533.73 (± 71.8)			
Week 360 (n=87)	557.05 (± 55.3)			
Week 384 (n=69)	549.57 (± 58.0)			
Week 408 (n=56)	586.95 (± 62.4)			
Week 432 (n=50)	569.09 (± 42.7)			
Week 456 (n=36)	561.16 (± 56.8)			
Week 480 (n=18)	652.16 (± 18.0)			
Week 504 (n=2)	668.04 (± 13.4)			
Week 528 (n=1)	910.00 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Concentration of C-Reactive Protein (CRP) in Blood

End point title	Concentration of C-Reactive Protein (CRP) in Blood

End point description:

Baseline was defined as last observation collected on or before day of first study drug administration in parent studies (2013-003752-21/2015-005431-41). All data from the time of randomization in the parent studies up to the end of study WN42349 for satralizumab-treated participants are reported here. All Participants-treated population included participants who received at least one dose of satralizumab at any time either during the parent studies or this study, irrespective of enrollment in current study. Number analyzed=participants with data available for analysis. "n"=participants with data available for

analysis at the specified timepoint. 99999=Geometric coefficient of variation was not evaluable as only 1 participant was analyzed.

End point type	Secondary

End point timeframe:

Baseline, every two weeks from Weeks 2 to 8; every 4 weeks from Weeks 12 to 192; every 24 weeks from Weeks 216 to 528

End point values	Satralizumab			
Subject group type	Reporting group			
Number of subjects analysed	165			
Units: milligrams/litre (mg/L)				
geometric mean (geometric coefficient of variation)				
Baseline (n=165)	1.27 (± 226.6)			
Week 2 (n=102)	0.38 (± 118.0)			
Week 4 (n=162)	0.36 (± 113.3)			
Week 8 (n=161)	0.39 (± 125.9)			
Week 12 (n=156)	0.42 (± 144.9)			
Week 16 (n=152)	0.42 (± 151.1)			
Week 20 (n=157)	0.41 (± 157.8)			
Week 24 (n=154)	0.44 (± 161.0)			
Week 28 (n=155)	0.41 (± 175.7)			
Week 32 (n=153)	0.44 (± 171.4)			
Week 36 (n=147)	0.43 (± 185.3)			
Week 40 (n=146)	0.48 (± 184.3)			
Week 44 (n=150)	0.43 (± 182.3)			
Week 48 (n=144)	0.44 (± 167.9)			
Week 52 (n=91)	0.50 (± 177.4)			
Week 56 (n=91)	0.47 (± 183.8)			
Week 60 (n=91)	0.49 (± 183.3)			
Week 64 (n=88)	0.47 (± 177.6)			
Week 68 (n=85)	0.52 (± 194.3)			
Week 72 (n=89)	0.50 (± 223.7)			
Week 76 (n=81)	0.51 (± 189.5)			
Week 80 (n=72)	0.51 (± 200.4)			
Week 84 (n=74)	0.53 (± 227.4)			
Week 88 (n=69)	0.51 (± 188.0)			
Week 92 (n=69)	0.51 (± 200.4)			
Week 96 (n=71)	0.52 (± 183.4)			
Week 100 (n=64)	0.52 (± 231.4)			
Week 104 (n=66)	0.46 (± 167.3)			
Week 108 (n=66)	0.51 (± 161.9)			
Week 112 (n=66)	0.48 (± 191.7)			
Week 116 (n=61)	0.43 (± 177.0)			
Week 120 (n=64)	0.52 (± 227.6)			
Week 124 (n=61)	0.56 (± 173.2)			
Week 128 (n=60)	0.57 (± 209.1)			
Week 132 (n=61)	0.59 (± 234.8)			
Week 136 (n=59)	0.54 (± 193.9)			

Week 140 (n=55)	0.61 (± 283.9)			
Week 144 (n=65)	0.47 (± 205.6)			
Week 148 (n=51)	0.47 (± 152.0)			
Week 152 (n=46)	0.51 (± 147.8)			
Week 156 (n=43)	0.47 (± 129.5)			
Week 160 (n=45)	0.48 (± 148.9)			
Week 164 (n=39)	0.49 (± 163.7)			
Week 168 (n=56)	0.45 (± 148.9)			
Week 172 (n=32)	0.45 (± 228.2)			
Week 176 (n=33)	0.39 (± 156.7)			
Week 180 (n=35)	0.42 (± 156.6)			
Week 184 (n=33)	0.38 (± 197.3)			
Week 188 (n=37)	0.46 (± 154.0)			
Week 192 (n=71)	0.40 (± 188.5)			
Week 216 (n=62)	0.30 (± 110.4)			
Week 240 (n=78)	0.40 (± 221.9)			
Week 264 (n=65)	0.36 (± 178.6)			
Week 288 (n=68)	0.36 (± 215.6)			
Week 312 (n=68)	0.32 (± 160.2)			
Week 336 (n=84)	0.48 (± 302.7)			
Week 360 (n=89)	0.39 (± 221.2)			
Week 384 (n=74)	0.37 (± 185.9)			
Week 408 (n=56)	0.29 (± 195.5)			
Week 432 (n=51)	0.35 (± 161.1)			
Week 456 (n=39)	0.32 (± 139.8)			
Week 480 (n=21)	0.17 (± 33.0)			
Week 504 (n=3)	0.15 (± 0.0)			
Week 528 (n=1)	0.15 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Concentration of Satralizumab at Specified Timepoints

End point title	Serum Concentration of Satralizumab at Specified Timepoints

End point description:

Baseline was defined as last observation collected on or before day of first study drug administration in parent studies (2013-003752-21/2015-005431-41). All data from the time of randomization in the parent studies up to the end of study WN42349 for satralizumab-treated participants are reported here. All Participants-treated population included participants who received at least one dose of satralizumab at any time either during the parent studies or this study, irrespective of enrollment in current study. Number analyzed is the number of participants with data available for analysis. "n"=participants with data available for analysis at the specified timepoint. 99999=Geometric coefficient of variation was not evaluable as only 1 participant was analyzed.

End point type	Secondary

End point timeframe:

Baseline, Week 2, Week 4, Week 5, Week 6; every 4 weeks from Weeks 8 to 192; every 24 weeks from Weeks 216 to 528

End point values	Satralizumab			
Subject group type	Reporting group			
Number of subjects analysed	164			
Units: nanograms/litre (ng/L)				
geometric mean (geometric coefficient of variation)				
Baseline (n=164)	103.75 (± 29.7)			
Week 2 (n=102)	7489.76 (± 102.8)			
Week 4 (n=155)	14631.06 (± 95.9)			
Week 5 (n=64)	20068.86 (± 105.6)			
Week 6 (n=62)	17495.09 (± 157.7)			
Week 8 (n=160)	12673.14 (± 190.9)			
Week 12 (n=158)	11031.23 (± 220.8)			
Week 16 (n=152)	10588.85 (± 250.6)			
Week 20 (n=157)	10065.62 (± 305.1)			
Week 24 (n=154)	10605.69 (± 306.1)			
Week 28 (n=154)	9730.68 (± 333.9)			
Week 32 (n=153)	10686.86 (± 282.5)			
Week 36 (n=146)	10036.31 (± 368.4)			
Week 40 (n=143)	9508.64 (± 400.1)			
Week 44 (n=150)	9891.10 (± 361.9)			
Week 48 (n=144)	11282.31 (± 311.3)			
Week 52 (n=93)	9585.58 (± 500.8)			
Week 56 (n=93)	9209.84 (± 468.2)			
Week 60 (n=91)	10090.62 (± 394.0)			
Week 64 (n=88)	9186.35 (± 376.7)			
Week 68 (n=83)	9951.51 (± 359.5)			
Week 72 (n=131)	10737.11 (± 340.8)			
Week 76 (n=82)	8414.98 (± 522.7)			
Week 80 (n=74)	8557.82 (± 431.6)			
Week 84 (n=77)	8208.84 (± 473.6)			
Week 88 (n=73)	8457.80 (± 498.3)			
Week 92 (n=71)	8316.17 (± 510.7)			

Week 96 (n=119)	10560.87 (± 329.6)			
Week 100 (n=70)	9841.13 (± 361.2)			
Week 104 (n=68)	11256.29 (± 278.2)			
Week 108 (n=71)	10521.75 (± 273.5)			
Week 112 (n=71)	10362.73 (± 314.0)			
Week 116 (n=63)	11219.11 (± 331.1)			
Week 120 (n=105)	11619.05 (± 315.4)			
Week 124 (n=66)	9680.42 (± 354.6)			
Week 128 (n=62)	8727.98 (± 362.3)			
Week 132 (n=65)	8378.76 (± 437.7)			
Week 136 (n=61)	10182.79 (± 294.2)			
Week 140 (n=57)	9731.57 (± 440.3)			
Week 144 (n=101)	11206.52 (± 328.4)			
Week 148 (n=56)	11605.26 (± 291.6)			
Week 152 (n=45)	12065.91 (± 352.8)			
Week 156 (n=45)	13017.85 (± 222.9)			
Week 160 (n=50)	13952.43 (± 173.1)			
Week 164 (n=43)	13869.87 (± 202.0)			
Week 168 (n=85)	14256.36 (± 183.0)			
Week 172 (n=42)	13018.63 (± 227.2)			
Week 176 (n=37)	11989.36 (± 330.9)			
Week 180 (n=42)	15333.00 (± 150.7)			
Week 184 (n=43)	16449.28 (± 101.1)			
Week 188 (n=43)	14519.13 (± 221.7)			
Week 192 (n=106)	11926.93 (± 284.9)			
Week 216 (n=123)	10582.11 (± 404.7)			
Week 240 (n=114)	13683.03 (± 237.7)			
Week 264 (n=116)	11576.23 (± 326.0)			
Week 288 (n=108)	13169.85 (± 221.9)			
Week 312 (n=96)	13007.87 (± 243.1)			
Week 336 (n=91)	10522.02 (± 407.6)			

Week 360 (n=87)	11604.67 (± 295.8)			
Week 384 (n=70)	14508.95 (± 303.3)			
Week 408 (n=56)	14652.75 (± 290.3)			
Week 432 (n=49)	13287.68 (± 329.1)			
Week 456 (n=36)	18532.35 (± 174.8)			
Week 480 (n=19)	26688.35 (± 56.3)			
Week 504 (n=2)	43917.08 (± 8.7)			
Week 528 (n=1)	57800.00 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Anti-Drug Antibodies (ADAs) from the First Dose of Satralizumab in Studies 2013-003752-21 and 2015-005431-41

End point title	Number of Participants with Anti-Drug Antibodies (ADAs) from the First Dose of Satralizumab in Studies 2013-003752-21 and 2015-005431-41

End point description:

Number of ADA-positive participants & ADA-negative participants at baseline (baseline prevalence) & after drug administration (post-baseline incidence) were summarized. Baseline evaluable participants = participants with an ADA assay result at baseline. Post-baseline evaluable participants = participants with an ADA assay from at least one post-baseline sample. Participants positive for ADA= number of participants with positive ADA result. Participants negative for ADA=number of participants with negative or missing baseline ADA result(s) & all negative post-baseline results. Baseline = last observation collected on or before day of first study drug administration in parent studies. All data from the time of randomization in the parent studies up to the end of study WN42349 for satralizumab-treated participants are reported here. All Participants-treated population is used for analysis. 'n'=number of participants with data available for analysis at the specified timepoint.

End point type	Secondary

End point timeframe:

First dose of satralizumab in parent studies up to 528 weeks

End point values	Satralizumab			
Subject group type	Reporting group			
Number of subjects analysed	166			
Units: participants				
Baseline|Positive (N=166)	3			
Post-baseline|Positive (N=164)	99			
Baseline|Negative (N=166)	161			
Post-baseline|Negative (N=164)	67			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline up to 523 weeks

Adverse event reporting additional description:

All Participants-treated population=all enrolled participants (in current study) who received at least 1 dose of satralizumab at any time either during parent studies or this study. First dosing visit in the current study or first satralizumab dosing visit in parent studies (2013-003752-21/2015-005431-41) was considered as baseline for this study.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.0

Reporting groups

Reporting group title	Satralizumab

Reporting group description:

Participants rolled over from studies 2013-003752-21 and 2015-005431-41 received satralizumab, 120 mg as SC injection, Q4W up to a maximum duration of 3 years in this study. Participants who received at least 1 dose of satralizumab at any time during parent studies or this study, irrespective of enrollment in current study are represented here.

Serious adverse events	Satralizumab		
Total subjects affected by serious adverse events			
subjects affected / exposed	44 / 166 (26.51%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer metastatic			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ovarian adenoma			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ovarian germ cell teratoma benign			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Uterine leiomyoma			
subjects affected / exposed	3 / 166 (1.81%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Aneurysm			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypertension			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Abortion			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Rehabilitation therapy			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Cervical dysplasia			
subjects affected / exposed	2 / 166 (1.20%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Ovarian cyst			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			

Apnoea				
subjects affected / exposed	1 / 166 (0.60%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary oedema				
subjects affected / exposed	1 / 166 (0.60%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Mental disorder				
subjects affected / exposed	1 / 166 (0.60%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Mental status changes				
subjects affected / exposed	2 / 166 (1.20%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Suicide attempt				
subjects affected / exposed	1 / 166 (0.60%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Fracture displacement				
subjects affected / exposed	1 / 166 (0.60%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Femur fracture				
subjects affected / exposed	1 / 166 (0.60%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Accidental overdose				
subjects affected / exposed	1 / 166 (0.60%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Accidental exposure to product			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fractured sacrum			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Road traffic accident			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Radius fracture			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Post procedural haematoma			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Post procedural complication			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Multiple injuries			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Limb fracture			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spinal compression fracture			

subjects affected / exposed	2 / 166 (1.20%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Bradycardia			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Acute myocardial infarction			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Migraine			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Neuromyelitis optica pseudo relapse			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Parkinsonism			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Seizure			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Tension headache			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			

Anaemia macrocytic			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Visual impairment			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Glaucoma			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Cataract			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Rectal haemorrhage			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pancreatitis acute			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Nausea			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intestinal perforation			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Enterocolitis				
subjects affected / exposed	1 / 166 (0.60%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Abdominal pain				
subjects affected / exposed	1 / 166 (0.60%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Intervertebral disc protrusion				
subjects affected / exposed	1 / 166 (0.60%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Systemic lupus erythematosus				
subjects affected / exposed	1 / 166 (0.60%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Non-cardiac chest pain				
subjects affected / exposed	1 / 166 (0.60%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatitis E				
subjects affected / exposed	1 / 166 (0.60%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Atypical mycobacterial infection				
subjects affected / exposed	1 / 166 (0.60%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	2 / 166 (1.20%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			

Hypothermia			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urosepsis			
subjects affected / exposed	2 / 166 (1.20%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	3 / 166 (1.81%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Sinusitis fungal			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Septic endocarditis			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis acute			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pulmonary sepsis			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia			

subjects affected / exposed	5 / 166 (3.01%)		
occurrences causally related to treatment / all	4 / 5		
deaths causally related to treatment / all	0 / 0		
Large intestine infection			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Influenza			
subjects affected / exposed	3 / 166 (1.81%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyperglycaemia			
subjects affected / exposed	1 / 166 (0.60%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Satralizumab		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	155 / 166 (93.37%)		
Investigations			
White blood cell count decreased			
subjects affected / exposed	13 / 166 (7.83%)		
occurrences (all)	30		
Lymphocyte count decreased			
subjects affected / exposed	11 / 166 (6.63%)		
occurrences (all)	17		
Complement factor C4 decreased			

subjects affected / exposed	9 / 166 (5.42%)		
occurrences (all)	11		
Blood fibrinogen decreased			
subjects affected / exposed	10 / 166 (6.02%)		
occurrences (all)	17		
Blood creatine phosphokinase increased			
subjects affected / exposed	10 / 166 (6.02%)		
occurrences (all)	12		
Blood cholesterol increased			
subjects affected / exposed	14 / 166 (8.43%)		
occurrences (all)	23		
Alanine aminotransferase increased			
subjects affected / exposed	14 / 166 (8.43%)		
occurrences (all)	20		
Injury, poisoning and procedural complications			
Ligament sprain			
subjects affected / exposed	9 / 166 (5.42%)		
occurrences (all)	11		
Injection related reaction			
subjects affected / exposed	24 / 166 (14.46%)		
occurrences (all)	57		
Fall			
subjects affected / exposed	11 / 166 (6.63%)		
occurrences (all)	21		
Vascular disorders			
Hypertension			
subjects affected / exposed	11 / 166 (6.63%)		
occurrences (all)	21		
Nervous system disorders			
Hypoaesthesia			
subjects affected / exposed	15 / 166 (9.04%)		
occurrences (all)	24		
Headache			
subjects affected / exposed	44 / 166 (26.51%)		
occurrences (all)	86		
Dizziness			

subjects affected / exposed	15 / 166 (9.04%)		
occurrences (all)	20		
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	16 / 166 (9.64%)		
occurrences (all)	26		
Leukopenia			
subjects affected / exposed	18 / 166 (10.84%)		
occurrences (all)	33		
Iron deficiency anaemia			
subjects affected / exposed	9 / 166 (5.42%)		
occurrences (all)	12		
Anaemia			
subjects affected / exposed	15 / 166 (9.04%)		
occurrences (all)	19		
Lymphopenia			
subjects affected / exposed	10 / 166 (6.02%)		
occurrences (all)	27		
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	11 / 166 (6.63%)		
occurrences (all)	12		
Vomiting			
subjects affected / exposed	9 / 166 (5.42%)		
occurrences (all)	11		
Toothache			
subjects affected / exposed	11 / 166 (6.63%)		
occurrences (all)	14		
Nausea			
subjects affected / exposed	21 / 166 (12.65%)		
occurrences (all)	27		
Diarrhoea			
subjects affected / exposed	21 / 166 (12.65%)		
occurrences (all)	42		
Dental caries			

subjects affected / exposed	10 / 166 (6.02%)		
occurrences (all)	10		
Constipation			
subjects affected / exposed	18 / 166 (10.84%)		
occurrences (all)	23		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	19 / 166 (11.45%)		
occurrences (all)	22		
Oropharyngeal pain			
subjects affected / exposed	17 / 166 (10.24%)		
occurrences (all)	21		
Psychiatric disorders			
Insomnia			
subjects affected / exposed	17 / 166 (10.24%)		
occurrences (all)	20		
Depression			
subjects affected / exposed	11 / 166 (6.63%)		
occurrences (all)	14		
Anxiety			
subjects affected / exposed	10 / 166 (6.02%)		
occurrences (all)	11		
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	26 / 166 (15.66%)		
occurrences (all)	43		
Myalgia			
subjects affected / exposed	15 / 166 (9.04%)		
occurrences (all)	16		
Back pain			
subjects affected / exposed	20 / 166 (12.05%)		
occurrences (all)	31		
Arthralgia			
subjects affected / exposed	35 / 166 (21.08%)		
occurrences (all)	43		
Infections and infestations			

Sinusitis				
subjects affected / exposed	16 / 166 (9.64%)			
occurrences (all)	22			
Oral herpes				
subjects affected / exposed	9 / 166 (5.42%)			
occurrences (all)	70			
Nasopharyngitis				
subjects affected / exposed	48 / 166 (28.92%)			
occurrences (all)	132			
Influenza				
subjects affected / exposed	13 / 166 (7.83%)			
occurrences (all)	14			
Gastroenteritis				
subjects affected / exposed	9 / 166 (5.42%)			
occurrences (all)	17			
Ear infection				
subjects affected / exposed	10 / 166 (6.02%)			
occurrences (all)	13			
Cystitis				
subjects affected / exposed	15 / 166 (9.04%)			
occurrences (all)	18			
COVID-19				
subjects affected / exposed	31 / 166 (18.67%)			
occurrences (all)	33			
Oedema peripheral				
subjects affected / exposed	11 / 166 (6.63%)			
occurrences (all)	13			
Fatigue				
subjects affected / exposed	17 / 166 (10.24%)			
occurrences (all)	22			
Eczema				
subjects affected / exposed	10 / 166 (6.02%)			
occurrences (all)	11			
Rash				
subjects affected / exposed	20 / 166 (12.05%)			
occurrences (all)	27			

Urinary tract infection subjects affected / exposed occurrences (all) Upper respiratory tract infection subjects affected / exposed occurrences (all)	 40 / 166 (24.10%) 139 46 / 166 (27.71%) 172		
Metabolism and nutrition disorders Hypercholesterolaemia subjects affected / exposed occurrences (all)	 9 / 166 (5.42%) 19		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported