



Clinical trial results:

A 24-month, open-label, prospective, multicenter, interventional, single-arm study assessing the efficacy and safety of fingolimod (Gilenya) 0.5 mg in relapsing multiple sclerosis (RMS) patients in China

Summary

EudraCT number	2024-000601-32
Trial protocol	Outside EU/EEA
Global end of trial date	25 March 2025

Results information

Result version number	v1 (current)
This version publication date	06 September 2025
First version publication date	06 September 2025

Trial information

Trial identification

Sponsor protocol code	CFTY720D2419
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04667949
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma AG
Sponsor organisation address	Lichtstrasse 36, Basel, Switzerland, 4056
Public contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, Novartis.email@Novartis.com
Scientific contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, Novartis.email@Novartis.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	25 March 2025
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	25 March 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective was to to evaluate the efficacy of fingolimod 0.5 mg on annualized relapse rate (ARR) in participants with RMS treated for up to 24 months.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 February 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	China: 98
Worldwide total number of subjects	98
EEA total number of subjects	0

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)	2
Adolescents (12-17 years)	9
Adults (18-64 years)	87
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled at 13 sites in China

Pre-assignment

Screening details:

There were up to 30 days of screening period (day -30 to -1) before first treatment (day 1).

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Fingolimod (< 18 years)

Arm description:

Fingolimod 0.5 mg capsule taken orally once daily in participants under 18 years old

Arm type	Experimental
Investigational medicinal product name	Fingolimod
Investigational medicinal product code	FTY720
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Fingolimod 0.5 mg capsule taken orally once daily

Arm title	Fingolimod > 18 years
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Arm description:

Fingolimod 0.5 mg capsule taken orally once daily in participants 18 years old or over

Arm type	Experimental
Investigational medicinal product name	Fingolimod
Investigational medicinal product code	FTY720
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Fingolimod 0.5 mg capsule taken orally once daily

Number of subjects in period 1	Fingolimod (< 18 years)	Fingolimod > 18 years
Started	11	87
Completed	10	75
Not completed	1	12
Physician decision	-	2
Subject decision	1	7

Adverse event, non-fatal	-	2
Lost to follow-up	-	1

Baseline characteristics

Reporting groups

Reporting group title	Fingolimod (< 18 years)
Reporting group description:	
Fingolimod 0.5 mg capsule taken orally once daily in participants under 18 years old	
Reporting group title	Fingolimod > 18 years
Reporting group description:	
Fingolimod 0.5 mg capsule taken orally once daily in participants 18 years old or over	

Reporting group values	Fingolimod (< 18 years)	Fingolimod > 18 years	Total
Number of subjects	11	87	98
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)	2	0	2
Adolescents (12-17 years)	9	0	9
Adults (18-64 years)	0	87	87
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous			
Units: years			
arithmetic mean	12.8	32.3	-
standard deviation	± 1.60	± 9.11	-
Sex: Female, Male			
Units: participants			
Female	3	51	54
Male	8	36	44
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	11	87	98
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	0	0	0
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Number of relapses in the last 12 months prior to screening			
Units: relapses/year			
arithmetic mean	1.7	1.2	-
standard deviation	± 1.27	± 0.47	-
Number of relapses in 12 to 24 months prior to screening			

Units: relapses/year			
arithmetic mean	0.8	0.7	
standard deviation	± 1.25	± 0.84	-

End points

End points reporting groups

Reporting group title	Fingolimod (< 18 years)
Reporting group description: Fingolimod 0.5 mg capsule taken orally once daily in participants under 18 years old	
Reporting group title	Fingolimod > 18 years
Reporting group description: Fingolimod 0.5 mg capsule taken orally once daily in participants 18 years old or over	

Primary: Adjusted Annualized relapse rate (ARR) in adult group

End point title	Adjusted Annualized relapse rate (ARR) in adult group ^{[1][2]}
End point description: A confirmed relapse is any relapse that is accompanied by an increase of at least 0.5 on the EDSS or an increase of 1 point on two different Functional Systems (FS) of the EDSS or 2 points on one of the FS (excluding Bowel/Bladder or Cerebral FS) as confirmed by the treating physician. The adjusted annualized relapse rate (ARR) was estimated by a negative binomial regression model with log-link function, the cumulative number of confirmed MS relapses per subject as the response variable, number of relapses in the previous two years before enrollment and baseline EDSS as continuous covariates. Natural log of time on study in years was used as the offset variable to account for the varying lengths of subjects' time in the study. The adjusted ARR (i.e.model-based estimate adjusted for covariates) and the corresponding 95% confidence interval were obtained. As per SAP this analysis was only performed for the Adult group. Descriptive data is presented in subsequent OMs.	
End point type	Primary
End point timeframe: Baseline to Month 24	

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 statistical hypothesis testing was planned for this primary endpoint

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per SAP this analysis was only performed for the Adult group.

End point values	Fingolimod > 18 years			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: relapses per participant-year				
number (confidence interval 95%)	0.018 (0.006 to 0.061)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with treatment emergent Adverse events (AE) and serious adverse events (SAE)

End point title	Number of participants with treatment emergent Adverse events (AE) and serious adverse events (SAE)
End point description: An adverse event (AE) is any untoward medical occurrence in a clinical investigation subject after providing written informed consent for participation in the study. For reporting purposes, the main focus was on treatment emergent adverse event (TEAE), defined as any AE which started on or after the day of first dose of study medication or events present prior to the start of treatment but increased in severity.	
End point type	Secondary
End point timeframe: From first dose of study treatment to 45 days after last study dose up to approximately 25.5 months	

End point values	Fingolimod (< 18 years)	Fingolimod > 18 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	87		
Units: participants				
Adverse events (AEs)	11	86		
Study treatment related AEs	10	81		
Serious adverse events (SAEs)	3	12		
AEs leading to interruption of study treatment	3	11		
AEs leading to study discontinuation	1	5		
AEs leading to death	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Annualized rate of the number of new or newly enlarged T2 lesions

End point title	Annualized rate of the number of new or newly enlarged T2 lesions ^[3]
End point description: Obtained from fitting a negative binomial regression model with log-link function, the total number of new or newly enlarged T2 lesions during the treatment period (per participant) as the response variable. The model included baseline age and volume of T2 lesions at baseline as continuous covariates. Natural log of time from screening scan in years was used as the offset. Baseline is defined as the last non-missing assessment obtained prior to the first administration of study drug. As per SAP this analysis was only performed for the Adult group.	
End point type	Secondary
End point timeframe: Baseline to end of treatment (up to Month 24)	

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As per SAP this analysis was only performed for the Adult group.

End point values	Fingolimod > 18 years			
Subject group type	Reporting group			
Number of subjects analysed	81			
Units: Lesions per participant-year				
number (confidence interval 95%)	1.316 (0.762 to 2.272)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in number of new or newly enlarged T2 lesions

End point title	Change from baseline in number of new or newly enlarged T2 lesions
End point description:	
Number of new/newly enlarged T2 lesions since baseline as measured by MRI	
End point type	Secondary
End point timeframe:	
Baseline up to Month 24	

End point values	Fingolimod (< 18 years)	Fingolimod > 18 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	81		
Units: new / newly enlarged T2 lesions				
arithmetic mean (standard deviation)				
12 months	1.8 (± 1.93)	1.8 (± 4.18)		
24 months	2.1 (± 2.18)	2.4 (± 4.84)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in T2 lesion volume

End point title	Change from baseline in T2 lesion volume
End point description:	
T2 lesion volume as measured by MRI and calculated as post-baseline value - baseline value	
End point type	Secondary
End point timeframe:	
Baseline up to Month 24	

End point values	Fingolimod (< 18 years)	Fingolimod > 18 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	79		
Units: milliliters				
median (full range (min-max))				
12 months	0.6140 (-17.607 to 34.748)	0.3930 (-6.343 to 25.158)		
24 months	-1.6736 (-17.100 to 36.719)	0.4065 (-5.741 to 26.322)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Gd-enhancing T1 lesions per scan in adult group

End point title	Number of Gd-enhancing T1 lesions per scan in adult group ^[4]
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End point description:

Obtained from fitting a negative binomial regression model with log-link function, the total number of Gd-enhancing T1 lesions during the treatment period (per patient) as the response variable.

The model included baseline age and number of Gd-enhancing T1 lesions at baseline as continuous covariates. Natural log of the number of MRI scans was used as the offset.

MRI scans were performed at baseline, month 12 and month 24 and End of treatment for participants that discontinued treatment. Unscheduled MRIs could be performed at the investigator's judgement. As per SAP this analysis was only performed for the Adult group.

End point type	Secondary
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End point timeframe:

Baseline up to Month 24

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per SAP this analysis was only performed for the Adult group.

End point values	Fingolimod > 18 years			
Subject group type	Reporting group			
Number of subjects analysed	80			
Units: Lesions per participant per scan				
number (confidence interval 95%)	0.376 (0.216 to 0.655)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Gd-enhancing T1 lesions

End point title	Number of Gd-enhancing T1 lesions
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End point description:

Number of Gd-enhancing T1 lesions as measured by MRI

End point type	Secondary
End point timeframe:	
Baseline up to Month 24	

End point values	Fingolimod (< 18 years)	Fingolimod > 18 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	79		
Units: T1 lesions				
arithmetic mean (standard deviation)				
12 months	0.4 (± 0.70)	0.4 (± 0.84)		
24 months	0 (± 0.00)	0.4 (± 1.83)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in Gd-enhancing T1 lesion volume

End point title	Change from baseline in Gd-enhancing T1 lesion volume
End point description:	
Gd-enhancing T1 lesion volume as measured by MRI and calculated as post-baseline value - baseline value	
End point type	Secondary
End point timeframe:	
Baseline up to Month 24	

End point values	Fingolimod (< 18 years)	Fingolimod > 18 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	79		
Units: microliters				
median (full range (min-max))				
12 months	-56.0 (-1392.5 to 418.0)	0.00 (-1869.0 to 546.0)		
24 months	-56.0 (-632.7 to 0.0)	0.00 (-1869.0 to 1082.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of T1 hypo-intense lesions

End point title	Number of T1 hypo-intense lesions
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End point description:	
Number of T1 hypo-intense lesions as measured by MRI	
End point type	Secondary
End point timeframe:	
Baseline up to Month 24	

End point values	Fingolimod (< 18 years)	Fingolimod > 18 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	79		
Units: T1 hypo-intense lesions				
arithmetic mean (standard deviation)				
12 months	14.6 (± 12.97)	17.0 (± 13.62)		
24 months	13.4 (± 10.86)	16.7 (± 13.27)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in T1 hypo-intense lesion volume

End point title	Change from baseline in T1 hypo-intense lesion volume
End point description:	
T1 hypo-intense lesions as measured by MRI and calculated as post-baseline value - baseline value	
End point type	Secondary
End point timeframe:	
Baseline up to Month 24	

End point values	Fingolimod (< 18 years)	Fingolimod > 18 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	79		
Units: microliters				
median (full range (min-max))				
12 months	-77.500 (-6849.30 to 20341.80)	44.000 (-4921.30 to 19035.00)		
24 months	-641.415 (-7444.50 to 1161.50)	187.100 (-5772.20 to 19264.00)		

Statistical analyses

No statistical analyses for this end point

Post-hoc: Participant based Annualized relapse rate (ARR)

End point title	Participant based Annualized relapse rate (ARR)
End point description: A relapse is an appearance of a new neurological abnormality or worsening of previously stable or improving pre-existing neurological abnormality, separated by at least 30 days from onset of a preceding clinical demyelinating event which is present for at least 24 hours in the absence of fever or infection. A relapse is confirmed by the treating physician when it is accompanied by an increase of at least 0.5 on the Expanded Disability Status Scale (EDSS) or an increase of 1 point on two different Functional Systems (FS) of the EDSS or 2 points on one of the FS (excluding Bowel/Bladder or Cerebral FS). Participant-based ARR was calculated by taking the total number of relapses observed for a participant divided by the total number of days in study of that participant and multiplied by 365.25.	
End point type	Post-hoc
End point timeframe: Baseline to Month 24	

End point values	Fingolimod (< 18 years)	Fingolimod > 18 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	87		
Units: relapses per participant-year				
arithmetic mean (standard deviation)				
All relapses - Participant based	0.1952 (± 0.50314)	0.0969 (± 0.50002)		
Confirmed relapses - Participant based	0.0460 (± 0.15253)	0.0372 (± 0.24424)		

Statistical analyses

No statistical analyses for this end point

Post-hoc: Time based Annualized relapse rate (ARR)

End point title	Time based Annualized relapse rate (ARR)
End point description: A relapse is an appearance of a new neurological abnormality or worsening of previously stable or improving pre-existing neurological abnormality, separated by at least 30 days from onset of a preceding clinical demyelinating event which is present for at least 24 hours in the absence of fever or infection. A relapse is confirmed by the treating physician when it is accompanied by an increase of at least 0.5 on the Expanded Disability Status Scale (EDSS) or an increase of 1 point on two different Functional Systems (FS) of the EDSS or 2 points on one of the FS (excluding Bowel/Bladder or Cerebral FS). Time-based ARR was calculated by taking the total number of relapses observed for all subjects within an age group divided by the total number of days in study of all subjects within the group and multiplied by 365.25 days.	
End point type	Post-hoc
End point timeframe: Baseline to Month 24	

End point values	Fingolimod (< 18 years)	Fingolimod > 18 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	87		
Units: relapses per participant-year				
number (not applicable)				
All relapses - Time based	0.161	0.065		
Confirmed relapses - Time based	0.054	0.019		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were reported from first dose of study treatment to 60 days after last study dose up to approximately 26 months

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	27.1
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Reporting groups

Reporting group title	Less than 18 years
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Reporting group description:

Less than 18 years

Reporting group title	Overall
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Reporting group description:

Overall

Reporting group title	Greater than or equal to 18 years
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Reporting group description:

Greater than or equal to 18 years

Serious adverse events	Less than 18 years	Overall	Greater than or equal to 18 years
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 11 (27.27%)	15 / 98 (15.31%)	12 / 87 (13.79%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Fractured sacrum			
subjects affected / exposed	0 / 11 (0.00%)	1 / 98 (1.02%)	1 / 87 (1.15%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			
subjects affected / exposed	0 / 11 (0.00%)	1 / 98 (1.02%)	1 / 87 (1.15%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Syncope			

subjects affected / exposed	1 / 11 (9.09%)	1 / 98 (1.02%)	0 / 87 (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
Acute disseminated encephalomyelitis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 98 (1.02%)	1 / 87 (1.15%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	1 / 11 (9.09%)	1 / 98 (1.02%)	0 / 87 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	2 / 11 (18.18%)	2 / 98 (2.04%)	0 / 87 (0.00%)
occurrences causally related to treatment / all	3 / 3	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion			
subjects affected / exposed	0 / 11 (0.00%)	1 / 98 (1.02%)	1 / 87 (1.15%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion complete			
subjects affected / exposed	0 / 11 (0.00%)	1 / 98 (1.02%)	1 / 87 (1.15%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Iridocyclitis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 98 (1.02%)	1 / 87 (1.15%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Drug-induced liver injury			

subjects affected / exposed	0 / 11 (0.00%)	2 / 98 (2.04%)	2 / 87 (2.30%)
occurrences causally related to treatment / all	0 / 0	2 / 2	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver injury			
subjects affected / exposed	0 / 11 (0.00%)	3 / 98 (3.06%)	3 / 87 (3.45%)
occurrences causally related to treatment / all	0 / 0	3 / 3	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Muscle twitching			
subjects affected / exposed	1 / 11 (9.09%)	1 / 98 (1.02%)	0 / 87 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 11 (0.00%)	2 / 98 (2.04%)	2 / 87 (2.30%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile infection			
subjects affected / exposed	1 / 11 (9.09%)	1 / 98 (1.02%)	0 / 87 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	1 / 11 (9.09%)	1 / 98 (1.02%)	0 / 87 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 11 (9.09%)	1 / 98 (1.02%)	0 / 87 (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
Tonsillitis			
subjects affected / exposed	1 / 11 (9.09%)	1 / 98 (1.02%)	0 / 87 (0.00%)
occurrences causally related to treatment / all	4 / 4	4 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Less than 18 years	Overall	Greater than or equal to 18 years
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 11 (100.00%)	96 / 98 (97.96%)	85 / 87 (97.70%)
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	1 / 11 (9.09%)	3 / 98 (3.06%)	2 / 87 (2.30%)
occurrences (all)	1	3	2
Chest discomfort			
subjects affected / exposed	1 / 11 (9.09%)	1 / 98 (1.02%)	0 / 87 (0.00%)
occurrences (all)	1	1	0
Influenza like illness			
subjects affected / exposed	1 / 11 (9.09%)	4 / 98 (4.08%)	3 / 87 (3.45%)
occurrences (all)	2	6	4
Pyrexia			
subjects affected / exposed	4 / 11 (36.36%)	16 / 98 (16.33%)	12 / 87 (13.79%)
occurrences (all)	6	20	14
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	1 / 11 (9.09%)	1 / 98 (1.02%)	0 / 87 (0.00%)
occurrences (all)	1	1	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 11 (18.18%)	12 / 98 (12.24%)	10 / 87 (11.49%)
occurrences (all)	4	16	12
Psychiatric disorders			
Initial insomnia			
subjects affected / exposed	1 / 11 (9.09%)	1 / 98 (1.02%)	0 / 87 (0.00%)
occurrences (all)	1	1	0
Investigations			

Alanine aminotransferase increased			
subjects affected / exposed	2 / 11 (18.18%)	35 / 98 (35.71%)	33 / 87 (37.93%)
occurrences (all)	3	59	56
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 11 (9.09%)	20 / 98 (20.41%)	19 / 87 (21.84%)
occurrences (all)	1	28	27
Blood cholesterol increased			
subjects affected / exposed	1 / 11 (9.09%)	2 / 98 (2.04%)	1 / 87 (1.15%)
occurrences (all)	1	2	1
Electrocardiogram PR shortened			
subjects affected / exposed	1 / 11 (9.09%)	4 / 98 (4.08%)	3 / 87 (3.45%)
occurrences (all)	1	4	3
Electrocardiogram ST segment abnormal			
subjects affected / exposed	1 / 11 (9.09%)	1 / 98 (1.02%)	0 / 87 (0.00%)
occurrences (all)	1	1	0
Electrocardiogram high voltage			
subjects affected / exposed	1 / 11 (9.09%)	1 / 98 (1.02%)	0 / 87 (0.00%)
occurrences (all)	3	3	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 11 (0.00%)	10 / 98 (10.20%)	10 / 87 (11.49%)
occurrences (all)	0	12	12
Liver function test abnormal			
subjects affected / exposed	2 / 11 (18.18%)	2 / 98 (2.04%)	0 / 87 (0.00%)
occurrences (all)	4	4	0
Lymphocyte count decreased			
subjects affected / exposed	2 / 11 (18.18%)	55 / 98 (56.12%)	53 / 87 (60.92%)
occurrences (all)	2	91	89
Lymphocyte percentage decreased			
subjects affected / exposed	1 / 11 (9.09%)	8 / 98 (8.16%)	7 / 87 (8.05%)
occurrences (all)	1	12	11
Monocyte count increased			
subjects affected / exposed	1 / 11 (9.09%)	1 / 98 (1.02%)	0 / 87 (0.00%)
occurrences (all)	1	1	0
Neutrophil count decreased			

subjects affected / exposed	2 / 11 (18.18%)	6 / 98 (6.12%)	4 / 87 (4.60%)
occurrences (all)	2	6	4
Neutrophil percentage increased			
subjects affected / exposed	1 / 11 (9.09%)	2 / 98 (2.04%)	1 / 87 (1.15%)
occurrences (all)	1	3	2
Platelet count increased			
subjects affected / exposed	1 / 11 (9.09%)	3 / 98 (3.06%)	2 / 87 (2.30%)
occurrences (all)	1	3	2
SARS-CoV-2 test positive			
subjects affected / exposed	1 / 11 (9.09%)	1 / 98 (1.02%)	0 / 87 (0.00%)
occurrences (all)	1	1	0
Protein urine present			
subjects affected / exposed	2 / 11 (18.18%)	3 / 98 (3.06%)	1 / 87 (1.15%)
occurrences (all)	3	4	1
Urinary sediment present			
subjects affected / exposed	1 / 11 (9.09%)	1 / 98 (1.02%)	0 / 87 (0.00%)
occurrences (all)	1	1	0
Weight increased			
subjects affected / exposed	4 / 11 (36.36%)	12 / 98 (12.24%)	8 / 87 (9.20%)
occurrences (all)	4	13	9
Weight decreased			
subjects affected / exposed	5 / 11 (45.45%)	13 / 98 (13.27%)	8 / 87 (9.20%)
occurrences (all)	5	15	10
White blood cell count decreased			
subjects affected / exposed	4 / 11 (36.36%)	26 / 98 (26.53%)	22 / 87 (25.29%)
occurrences (all)	7	48	41
White blood cell count increased			
subjects affected / exposed	1 / 11 (9.09%)	2 / 98 (2.04%)	1 / 87 (1.15%)
occurrences (all)	1	2	1
White blood cells urine positive			
subjects affected / exposed	2 / 11 (18.18%)	10 / 98 (10.20%)	8 / 87 (9.20%)
occurrences (all)	3	14	11
Cardiac disorders			
Sinus bradycardia			
subjects affected / exposed	0 / 11 (0.00%)	13 / 98 (13.27%)	13 / 87 (14.94%)
occurrences (all)	0	15	15

Ventricular extrasystoles subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	1 / 98 (1.02%) 1	0 / 87 (0.00%) 0
Nervous system disorders			
Dizziness subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	5 / 98 (5.10%) 5	4 / 87 (4.60%) 4
Headache subjects affected / exposed occurrences (all)	2 / 11 (18.18%) 4	12 / 98 (12.24%) 18	10 / 87 (11.49%) 14
Seizure subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	1 / 98 (1.02%) 1	0 / 87 (0.00%) 0
Syncope subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 2	2 / 98 (2.04%) 3	1 / 87 (1.15%) 1
Blood and lymphatic system disorders			
Hypoglobulinaemia subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	3 / 98 (3.06%) 3	2 / 87 (2.30%) 2
Leukopenia subjects affected / exposed occurrences (all)	5 / 11 (45.45%) 10	27 / 98 (27.55%) 45	22 / 87 (25.29%) 35
Neutropenia subjects affected / exposed occurrences (all)	3 / 11 (27.27%) 4	5 / 98 (5.10%) 7	2 / 87 (2.30%) 3
Lymphopenia subjects affected / exposed occurrences (all)	7 / 11 (63.64%) 9	31 / 98 (31.63%) 44	24 / 87 (27.59%) 35
Ear and labyrinth disorders			
Cerumen impaction subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	2 / 98 (2.04%) 2	1 / 87 (1.15%) 1
Eye disorders			
Conjunctivitis allergic subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	1 / 98 (1.02%) 1	0 / 87 (0.00%) 0

Ocular hypertension subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	1 / 98 (1.02%) 1	0 / 87 (0.00%) 0
Refraction disorder subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	1 / 98 (1.02%) 1	0 / 87 (0.00%) 0
Strabismus subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	1 / 98 (1.02%) 1	0 / 87 (0.00%) 0
Gastrointestinal disorders			
Abdominal pain subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 3	2 / 98 (2.04%) 4	1 / 87 (1.15%) 1
Diarrhoea subjects affected / exposed occurrences (all)	3 / 11 (27.27%) 3	8 / 98 (8.16%) 9	5 / 87 (5.75%) 6
Haematemesis subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	1 / 98 (1.02%) 1	0 / 87 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	2 / 11 (18.18%) 5	3 / 98 (3.06%) 6	1 / 87 (1.15%) 1
Nausea subjects affected / exposed occurrences (all)	2 / 11 (18.18%) 2	3 / 98 (3.06%) 3	1 / 87 (1.15%) 1
Hepatobiliary disorders			
Hepatic function abnormal subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	10 / 98 (10.20%) 11	10 / 87 (11.49%) 11
Skin and subcutaneous tissue disorders			
Alopecia subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	6 / 98 (6.12%) 6	6 / 87 (6.90%) 6
Nail bed inflammation subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	1 / 98 (1.02%) 1	0 / 87 (0.00%) 0
Hair colour changes			

subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	1 / 98 (1.02%) 1	0 / 87 (0.00%) 0
Neurodermatitis subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	1 / 98 (1.02%) 1	0 / 87 (0.00%) 0
Renal and urinary disorders Leukocyturia subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	1 / 98 (1.02%) 1	0 / 87 (0.00%) 0
Urine abnormality subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	1 / 98 (1.02%) 1	0 / 87 (0.00%) 0
Musculoskeletal and connective tissue disorders Muscle twitching subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 2	1 / 98 (1.02%) 2	0 / 87 (0.00%) 0
Infections and infestations Bronchitis subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	1 / 98 (1.02%) 1	0 / 87 (0.00%) 0
Tonsillitis subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 6	1 / 98 (1.02%) 6	0 / 87 (0.00%) 0
Nasopharyngitis subjects affected / exposed occurrences (all)	4 / 11 (36.36%) 5	13 / 98 (13.27%) 16	9 / 87 (10.34%) 11
Gingivitis subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	2 / 98 (2.04%) 2	1 / 87 (1.15%) 1
COVID-19 subjects affected / exposed occurrences (all)	2 / 11 (18.18%) 3	37 / 98 (37.76%) 39	35 / 87 (40.23%) 36
Pharyngitis subjects affected / exposed occurrences (all)	4 / 11 (36.36%) 4	4 / 98 (4.08%) 4	0 / 87 (0.00%) 0
Upper respiratory tract infection			

subjects affected / exposed	4 / 11 (36.36%)	25 / 98 (25.51%)	21 / 87 (24.14%)
occurrences (all)	12	43	31
Urinary tract infection			
subjects affected / exposed	0 / 11 (0.00%)	16 / 98 (16.33%)	16 / 87 (18.39%)
occurrences (all)	0	24	24
Metabolism and nutrition disorders			
Hyperlipidaemia			
subjects affected / exposed	0 / 11 (0.00%)	9 / 98 (9.18%)	9 / 87 (10.34%)
occurrences (all)	0	11	11

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 August 2020	• Added detailed pulmonary function monitoring guidance. • Updated the description of severe uncontrolled respiratory disease in pulmonary function test. • Revised the Liver Safety Monitoring Guidance according to the China fingolimod label. • Clarified the ECG requirement for baseline and first dose monitoring. • Clearly defined the 6m-CDP as measured by EDSS. • Updated protocol to adapt to the ongoing COVID-19 pandemic.
11 October 2021	• Introduced the measures in response to public health emergencies (e.g. COVID-19 pandemic). • Updated the ophthalmic guidance on diagnosis of macular edema. • Removed the maximum 5 days requirement for the use of corticosteroids. • Removed proton density in the efficacy assessment. • Changed the language regarding new findings in MRI images. • Clarified the detailed definition of highly effective contraception.
13 June 2023	• Clarified and detailed the identification and situation when EOS visit was required in the study. • Described more clearly about the analysis of T2 lesion-related MRI parameters that were analyzed as secondary endpoints. • Updated language to align with the Novartis protocol template Version 5.0.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported