Clinical trial results:
A Phase 2, Randomized, Placebo-Controlled Study to Evaluate Safety, Tolerability, and Efficacy of TAK-079 in Patients With Generalized Myasthenia Gravis

Summary

EudraCT number	2019-003383-47
Trial protocol	IT
Global end of trial date	12 July 2022

Results information

Result version number	v1 (current)
This version publication date	19 April 2023
First version publication date	19 April 2023

Trial information

Trial identification

Sponsor protocol code	TAK-079-1005

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04159805
WHO universal trial number (UTN)	U1111-1234-4442

Notes:

Sponsors

Sponsor organisation name	Takeda
Sponsor organisation address	95 Hayden Avenue, Lexington, United States, MA 02421
Public contact	Study Director, Takeda, +1 877-825-3327, TrialDisclosures@takeda.com
Scientific contact	Study Director, Takeda, +1 877-825-3327, TrialDisclosures@takeda.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?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	12 July 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	12 July 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this trial is to evaluate the safety and tolerability of TAK-079 in participants with generalized myasthenia gravis (MG) who are receiving stable background therapy for MG.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 January 2020
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	Canada: 2
Country: Number of subjects enrolled	Poland: 5
Country: Number of subjects enrolled	Serbia: 17
Country: Number of subjects enrolled	Spain: 4
Country: Number of subjects enrolled	United States: 8
Worldwide total number of subjects	36
EEA total number of subjects	9

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	31
From 65 to 84 years	5

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants took part in the study at 15 investigative sites in the United States, Spain, Poland, Serbia, and Canada from 14 January 2020 to 12 July 2022.

Pre-assignment

Screening details:

Participants with a diagnosis of Myasthenia Gravis (MG) were enrolled in 1:1:1 ratio to receive TAK-079 matching placebo, TAK-079 300 mg or TAK-079 600 mg in combination with standard background therapy.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	TAK-079 Placebo-matching

Arm description:

TAK-079 placebo-matching injection, subcutaneously (SC), once weekly in combination with standard background therapy for 8 weeks.

Arm type	Placebo
Investigational medicinal product name	TAK-079 Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

TAK-079 placebo-matching SC injection

Arm title	TAK-079 300 mg

Arm description:

TAK-079 300 mg injection, SC, once weekly in combination with standard background therapy for 8 weeks.

Arm type	Experimental
Investigational medicinal product name	TAK-079
Investigational medicinal product code	
Other name	Mezagitamab
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

TAK-079 SC injection

Arm title	TAK-079 600 mg

Arm description:

TAK-079 600 mg injection, SC, once weekly in combination with standard background therapy for 8 weeks.

Arm type	Experimental

Investigational medicinal product name	TAK-079
Investigational medicinal product code	
Other name	Mezagitamab
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

TAK-079 SC injection

Number of subjects in period 1	TAK-079 Placebo-matching	TAK-079 300 mg	TAK-079 600 mg
Started	12	12	12
Completed	12	10	10
Not completed	0	2	2
Consent withdrawn by subject	-	2	2

Baseline characteristics

Reporting groups	
Reporting group title	TAK-079 Placebo-matching
Reporting group description:	
TAK-079 placebo-matching injection, subcutaneously (SC), once weekly in combination with standard background therapy for 8 weeks.	
Reporting group title	TAK-079 300 mg
Reporting group description:	
TAK-079 300 mg injection, SC, once weekly in combination with standard background therapy for 8 weeks.	
Reporting group title	TAK-079 600 mg
Reporting group description:	
TAK-079 600 mg injection, SC, once weekly in combination with standard background therapy for 8 weeks.	

Reporting group values	TAK-079 Placebo-matching	TAK-079 300 mg	TAK-079 600 mg
Number of subjects	12	12	12
Age Categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	46.5	45.3	56.3
standard deviation	± 18.03	± 12.47	± 14.42
Gender categorical Units: Subjects			
Female	9	6	7
Male	3	6	5
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	2	0	1
Not Hispanic or Latino	9	12	11
Unknown or Not Reported	1	0	0
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	0	0
White	10	12	11
More than one race	0	0	0
Unknown or Not Reported	1	0	0
Region of Enrollment Units: Subjects			
Canada Canada	0	1	1
Poland Poland	1	2	2
Serbia Serbia	5	7	5
Spain Spain	3	0	1

United States United States	3	2	3

Weight			
Units: kg			
arithmetic mean	85.11	86.28	88.38
standard deviation	± 25.607	± 21.132	± 25.672
Height			
Units: cm			
arithmetic mean	164.67	175.39	171.38
standard deviation	± 9.435	± 8.911	± 10.910
Quantitative Myasthenia Gravis (QMG) Scale Score at Baseline			
Physician-reported scale to assess MG disease severity by quantifying several body functions by physical exam. Each question is graded on a 4-point scale from 0=normal to 3=severe with a total score of 0 to 39; the higher score indicates greater disease burden.			
Units: score on a scale			
arithmetic mean	11.4	12.9	12.8
standard deviation	± 5.21	± 6.47	± 4.26
Myasthenia Gravis Composite (MGC) Scale Score at Baseline			
An assessment scale of MG disease activity based on a combination of participant- and physician-reported items. Each question is graded on 4 levels of impact from normal to severe with a total score of 0 to 50; the higher score indicates worse MG disease activity.			
Units: score on a scale			
arithmetic mean	14.7	16.8	15.3
standard deviation	± 5.80	± 6.58	± 6.00
Revised 15-item Myasthenia Gravis Quality of Life Scale (MG-QoL15r) Scale Score at Baseline			
A participant-reported score that assesses the participant's perception of impairment and disability and the degree to which the patient tolerates disease manifestations. Each question is graded on a 3-point scale from 0=normal to 2=severe with a total score of 0 to 30; the higher score indicates worse MG disease activity.			
Units: score on a scale			
arithmetic mean	11.5	17.1	13.9
standard deviation	± 4.15	± 6.76	± 4.72
Body Mass Index (BMI)			
BMI=[weight(kg) / height(m)^2].			
Units: kg/m^2			
arithmetic mean	31.33	27.74	30.22
standard deviation	± 8.867	± 4.852	± 9.315
Myasthenia Gravis Activities of Daily Living (MG-ADL) Scale Score at Baseline			
Participant-reported scale to assess MG symptoms to evaluate capacity to perform activities of daily living. Each question is graded on a 4-point scale from 0=normal to 3=severe with a total score of 0 to 24; the higher score indicates greater functional impairment and disability.			
Units: score on a scale			
arithmetic mean	7.9	9.3	8.4
standard deviation	± 1.78	± 2.49	± 2.23

Reporting group values	Total		
Number of subjects	36		

Age Categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	- -		
Gender categorical Units: Subjects			
Female	22		
Male	14		
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	3		
Not Hispanic or Latino	32		
Unknown or Not Reported	1		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0		
Asian	1		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	1		
White	33		
More than one race	0		
Unknown or Not Reported	1		
Region of Enrollment Units: Subjects			
Canada Canada	2		
Poland Poland	5		
Serbia Serbia	17		
Spain Spain	4		
United States United States	8		
Weight Units: kg arithmetic mean standard deviation	- -		
Height Units: cm arithmetic mean standard deviation	- -		
Quantitative Myasthenia Gravis (QMG) Scale Score at Baseline			
Physician-reported scale to assess MG disease severity by quantifying several body functions by physical exam. Each question is graded on a 4-point scale from 0=normal to 3=severe with a total score of 0 to 39; the higher score indicates greater disease burden.			
Units: score on a scale arithmetic mean standard deviation	- -		
Myasthenia Gravis Composite (MGC) Scale Score at Baseline			
An assessment scale of MG disease activity based on a combination of participant- and physician-reported items. Each question is graded on 4 levels of impact from normal to severe with a total score of			

0 to 50; the higher score indicates worse MG disease activity.			
Units: score on a scale arithmetic mean standard deviation	- 		
Revised 15-item Myasthenia Gravis Quality of Life Scale (MG-QoL15r) Scale Score at Baseline			
A participant-reported score that assesses the participant's perception of impairment and disability and the degree to which the patient tolerates disease manifestations. Each question is graded on a 3-point scale from 0=normal to 2=severe with a total score of 0 to 30; the higher score indicates worse MG disease activity.			
Units: score on a scale arithmetic mean standard deviation	- 		
Body Mass Index (BMI)			
BMI=[weight(kg) / height(m)^2].			
Units: kg/m^2 arithmetic mean standard deviation	- 		
Myasthenia Gravis Activities of Daily Living (MG-ADL) Scale Score at Baseline			
Participant-reported scale to assess MG symptoms to evaluate capacity to perform activities of daily living. Each question is graded on a 4-point scale from 0=normal to 3=severe with a total score of 0 to 24; the higher score indicates greater functional impairment and disability.			
Units: score on a scale arithmetic mean standard deviation	- 		

End points

End points reporting groups

Reporting group title	TAK-079 Placebo-matching
Reporting group description:	
TAK-079 placebo-matching injection, subcutaneously (SC), once weekly in combination with standard background therapy for 8 weeks.	
Reporting group title	TAK-079 300 mg
Reporting group description:	
TAK-079 300 mg injection, SC, once weekly in combination with standard background therapy for 8 weeks.	
Reporting group title	TAK-079 600 mg
Reporting group description:	
TAK-079 600 mg injection, SC, once weekly in combination with standard background therapy for 8 weeks.	

Primary: Percentage of Participants With Treatment Emergent Adverse Events (TEAEs), Serious Adverse Events (SAEs), Grade 3 or Higher TEAEs, and Adverse Event (AE) Leading to TAK-079 Discontinuation

End point title	Percentage of Participants With Treatment Emergent Adverse Events (TEAEs), Serious Adverse Events (SAEs), Grade 3 or Higher TEAEs, and Adverse Event (AE) Leading to TAK-079 Discontinuation[1]
End point description:	
AE=any untoward medical occurrence in clinical investigation participant administered drug;does not necessarily have to have causal relationship with this treatment.TEAE=AE with onset that occurs after receiving study drug.SAE is AE resulting in any of following outcomes or deemed significant for any other reason:death;initial or prolonged inpatient hospitalization;life-threatening experience(immediate risk of dying); persistent or significant disability/incapacity;congenital anomaly.Severity of TEAEs was graded using National cancer institute-Common Terminology Criteria for Adverse Events(NCI-CTCAE) version 4.03 definitions of Grade 1 through Grade 5 where Grade 1=mild symptoms,Grade 2=moderate symptoms,Grade 3=Severe or medically significant but not immediately life-threatening,Grade 4=life-threatening consequences and Grade 5=death related to AEs.Percentages are rounded off to whole number at single decimal. Safety Analysis Set=participants receiving at least 1 dose of study drug.	
End point type	Primary
End point timeframe:	
From signing the informed consent form up to end of long-term follow-up (up to Week 32)	
Notes:	
[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point. Justification: Only descriptive statistical analysis was performed for this endpoint.	

End point values	TAK-079 Placebo-matching	TAK-079 300 mg	TAK-079 600 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12	12	12	
Units: percentage of participants				
number (not applicable)				
TEAE	66.7	75.0	91.7	
SAE	8.3	8.3	8.3	
Grade 3 or Higher TEAEs	16.7	8.3	8.3	
AE Leading to TAK-079 Discontinuation	0.0	0.0	0.0	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Myasthenia Gravis Activities of Daily Living (MG-ADL) Scale Score

End point title	Change From Baseline in Myasthenia Gravis Activities of Daily Living (MG-ADL) Scale Score

End point description:

Participant-reported scale to assess MG symptoms to evaluate capacity to perform activities of daily living. Each question is graded on a 4-point scale from 0=normal to 3=severe with a total score of 0 to 24; the higher score indicates greater functional impairment and disability. Negative change indicates improvement. Mixed-effects model for repeated measures (MMRM) was used for the analysis. Full Analysis Set included all randomised participants who had baseline and at least 1 post-baseline efficacy assessment. n=Number analysed is the number of participants available for analysis at the specified timepoint. 9999=Data not reported for 0 participants.

End point type	Secondary

End point timeframe:

Baseline up to Week 32

End point values	TAK-079 Placebo-matching	TAK-079 300 mg	TAK-079 600 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12	12	12	
Units: score on a scale				
arithmetic mean (standard deviation)				
Change From Baseline at Week 4(n=12,12,12)	-2.8 (± 2.67)	-2.5 (± 2.47)	-1.8 (± 1.66)	
Change From Baseline at Week 6(n=12,11,11)	-4.0 (± 2.73)	-4.2 (± 2.64)	-2.3 (± 2.15)	
Change From Baseline at Week 8(n=12,11,12)	-3.8 (± 2.80)	-4.3 (± 3.10)	-2.0 (± 3.16)	
Change From Baseline at Week 10(n=11,11,11)	-4.0 (± 3.52)	-5.0 (± 2.41)	-2.0 (± 2.79)	
Change From Baseline at Week 12(n=11,11,12)	-4.2 (± 3.19)	-4.2 (± 2.56)	-2.5 (± 2.68)	
Change From Baseline at Week 14(n=11,10,10)	-4.0 (± 4.38)	-4.8 (± 2.20)	-2.0 (± 3.30)	
Change From Baseline at Week 16(n=10,10,10)	-4.1 (± 3.21)	-4.3 (± 2.79)	-3.1 (± 3.48)	
Change From Baseline at Week 20(n=0,8,11)	9999 (± 9999)	-3.9 (± 3.60)	-2.9 (± 3.11)	
Change From Baseline at Week 24(n=0,9,9)	9999 (± 9999)	-4.1 (± 3.62)	-3.0 (± 3.57)	
Change From Baseline at Week 28(n=0,10,9)	9999 (± 9999)	-3.9 (± 3.96)	-3.1 (± 3.37)	
Change From Baseline at Week 32(n=0,9,8)	9999 (± 9999)	-2.3 (± 4.61)	-2.8 (± 3.99)	

Statistical analyses

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
Change From Baseline at Week 4	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.299 [2]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.94
upper limit	2.97

Notes:

[2] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
Change From Baseline at Week 4	
Comparison groups	TAK-079 300 mg v TAK-079 Placebo-matching
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.772 [3]
Method	MMRM
Parameter estimate	Difference in Least Square (LS) Mean
Point estimate	0.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.72
upper limit	2.3

Notes:

[3] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 5
Statistical analysis description:	
Change From Baseline at Week 8	

Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.887 [4]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-0.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.82
upper limit	2.45

Notes:

[4] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 6

Statistical analysis description:

Change From Baseline at Week 8

Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.162 [5]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	1.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.76
upper limit	4.36

Notes:

[5] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 4

Statistical analysis description:

Change From Baseline at Week 6

Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.091 [6]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	1.86

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.32
upper limit	4.04

Notes:

[6] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 3
Statistical analysis description:	
Change From Baseline at Week 6	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.924 [7]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-0.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.34
upper limit	2.13

Notes:

[7] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 7
Statistical analysis description:	
Change From Baseline at Week 10	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.784 [8]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-0.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.01
upper limit	2.29

Notes:

[8] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 9

Statistical analysis description:	
Change From Baseline at Week 12	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.724 [9]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	0.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.98
upper limit	2.82

Notes:

[9] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 8
Statistical analysis description:	
Change From Baseline at Week 10	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.166 [10]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	1.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.79
upper limit	4.37

Notes:

[10] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 10
Statistical analysis description:	
Change From Baseline at Week 12	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.124 [11]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	1.81

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.52
upper limit	4.14

Notes:

[11] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 11
Statistical analysis description:	
Change From Baseline at Week 14	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.856 [12]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	0.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.91
upper limit	3.48

Notes:

[12] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 13
Statistical analysis description:	
Change From Baseline at Week 16	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.944 [13]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	0.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.14
upper limit	3.37

Notes:

[13] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 12

Statistical analysis description:	
Change From Baseline at Week 14	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.292 [14]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	1.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.48
upper limit	4.76

Notes:

[14] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 14
Statistical analysis description:	
Change From Baseline at Week 16	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.589 [15]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.33
upper limit	4.02

Notes:

[15] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Secondary: Change From Baseline in Quantitative Myasthenia Gravis (QMG) Scale Score

End point title	Change From Baseline in Quantitative Myasthenia Gravis (QMG) Scale Score

End point description:

Physician-reported scale to assess MG disease severity by quantifying several body functions by physical exam. Each question is graded on a 4-point scale from 0=normal to 3=severe with a total score of 0 to 39; the higher score indicates greater disease burden. Negative change indicates improvement. MMRM was used for the analysis. Full Analysis Set included all randomised participants who had baseline and at least 1 post-baseline efficacy assessment. n=Number analysed is the number of participants available for analysis at the specified timepoint. 9999=Dta was not collected for 0 participants.

End point type	Secondary

End point timeframe:

Baseline up to Week 32

End point values	TAK-079 Placebo-matching	TAK-079 300 mg	TAK-079 600 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12	12	12	
Units: score on a scale				
arithmetic mean (standard deviation)				
Change From Baseline at Week 4(n=12,12,12)	-1.0 (± 2.34)	-2.0 (± 2.70)	-0.2 (± 2.89)	
Change From Baseline at Week 6(n=11,12,12)	-0.9 (± 1.76)	-2.5 (± 3.24)	-1.3 (± 3.10)	
Change From Baseline at Week 8(n=12,11,11)	-1.0 (± 2.30)	-3.4 (± 3.35)	-0.9 (± 3.27)	
Change From Baseline at Week 10(n=11,11,11)	-1.4 (± 2.87)	-3.2 (± 3.09)	-0.7 (± 4.03)	
Change From Baseline at Week 12(n=11,11,12)	-2.8 (± 2.68)	-3.9 (± 2.55)	-0.8 (± 3.51)	
Change From Baseline at Week 14(n=11,10,10)	-1.9 (± 3.11)	-3.5 (± 2.51)	-0.6 (± 4.65)	
Change From Baseline at Week 16(n=10,10,10)	-1.2 (± 3.22)	-3.3 (± 3.43)	-0.3 (± 4.81)	
Change From Baseline at Week 20(n=0,8,11)	9999 (± 9999)	-1.9 (± 3.56)	-0.5 (± 4.27)	
Change From Baseline at Week 24(n=0,9,9)	9999 (± 9999)	-2.2 (± 4.47)	-0.6 (± 3.78)	
Change From Baseline at Week 28(n=0,10,9)	9999 (± 9999)	-1.7 (± 3.80)	-0.8 (± 4.52)	
Change From Baseline at Week 32(n=0,9,8)	9999 (± 9999)	-0.7 (± 4.27)	-0.1 (± 4.79)	

Statistical analyses

Statistical analysis title	Statistical Analysis 3
Statistical analysis description: Change From Baseline at Week 6	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.463 [16]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.53
upper limit	1.65

Notes:

[16] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
Change From Baseline at Week 4	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.418 [17]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.34
upper limit	3.14

Notes:

[17] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
Change From Baseline at Week 4	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.406 [18]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.17
upper limit	1.31

Notes:

[18] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 6
Statistical analysis description:	
Change From Baseline at Week 8	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg

Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.687 [19]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	0.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.1
upper limit	3.13

Notes:

[19] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 5
Statistical analysis description:	
Change From Baseline at Week 8	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.17 [20]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-1.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.41
upper limit	0.82

Notes:

[20] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 4
Statistical analysis description:	
Change From Baseline at Week 6	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.936 [21]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-0.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.7
upper limit	2.49

Notes:

[21] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 7
Statistical analysis description:	
Change From Baseline at Week 10	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.374 [22]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-1.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.05
upper limit	1.57

Notes:

[22] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 10
Statistical analysis description:	
Change From Baseline at Week 12	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.106 [23]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	2.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.48
upper limit	4.71

Notes:

[23] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 9

Statistical analysis description:	
Change From Baseline at Week 12	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.69 [24]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-0.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.12
upper limit	2.09

Notes:

[24] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 8
Statistical analysis description:	
Change From Baseline at Week 10	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.478 [25]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.82
upper limit	3.8

Notes:

[25] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 13
Statistical analysis description:	
Change From Baseline at Week 16	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.431 [26]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-1.37

Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.91
upper limit	2.17

Notes:

[26] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 12
Statistical analysis description:	
Change From Baseline at Week 14	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.144 [27]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	2.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.81
upper limit	5.18

Notes:

[27] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 11
Statistical analysis description:	
Change From Baseline at Week 14	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.547 [28]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-0.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.89
upper limit	2.12

Notes:

[28] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 14

Statistical analysis description:	
Change From Baseline at Week 16	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.488
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.34
upper limit	4.74

Secondary: Change From Baseline in Myasthenia Gravis Composite (MGC) Scale Score

End point title	Change From Baseline in Myasthenia Gravis Composite (MGC) Scale Score

End point description:

An assessment scale of MG disease activity based on a combination of participant- and physician-reported items. Each question is graded on 4 levels of impact from normal to severe with a total score of 0 to 50; the higher score indicates worse MG disease activity. Negative change indicates improvement. MMRM was used for the analysis. Full Analysis Set included all randomised participants who had baseline and at least 1 post-baseline efficacy assessment. n=Number analysed is the number of participants available for analysis at the specified timepoint. 9999=Data was not reported for 0 participants.

End point type	Secondary

End point timeframe:

Baseline up to Week 32

End point values	TAK-079 Placebo-matching	TAK-079 300 mg	TAK-079 600 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12	12	12	
Units: score on a scale				
arithmetic mean (standard deviation)				
Change From Baseline at Week 4(n=12,12,12)	-4.2 (± 3.69)	-4.9 (± 3.82)	-1.1 (± 5.92)	
Change From Baseline at Week 6(n=12,11,11)	-7.3 (± 4.29)	-6.1 (± 5.24)	-4.9 (± 4.74)	
Change From Baseline at Week 8(n=11,11,12)	-5.5 (± 4.03)	-7.4 (± 4.63)	-2.4 (± 6.10)	
Change From Baseline at Week 10(n=11,11,11)	-7.8 (± 5.86)	-7.6 (± 5.07)	-2.6 (± 6.55)	
Change From Baseline at Week 12(n=11,11,12)	-7.3 (± 5.00)	-8.5 (± 3.11)	-5.1 (± 5.11)	
Change From Baseline at Week 14(n=11,10,10)	-6.1 (± 6.52)	-9.7 (± 3.83)	-0.9 (± 8.25)	

Change From Baseline at Week 16(n=10,10,10)	-6.6 (± 4.95)	-9.2 (± 5.18)	-2.9 (± 6.45)	
Change From Baseline at Week 20(n=0,8,11)	9999 (± 9999)	-7.3 (± 5.20)	-2.6 (± 7.21)	
Change From Baseline at Week 24(n=0,9,9)	9999 (± 9999)	-7.1 (± 5.78)	-3.3 (± 7.30)	
Change From Baseline at Week 28(n=0,10,9)	9999 (± 9999)	-5.6 (± 6.40)	-4.1 (± 7.59)	
Change From Baseline at Week 32(n=0,9,8)	9999 (± 9999)	-3.4 (± 8.13)	-2.5 (± 8.07)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: Change From Baseline at Week 4	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.855 [29]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-0.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.14
upper limit	3.45

Notes:

[29] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 6
Statistical analysis description: Change From Baseline at Week 8	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.13 [30]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	3.26
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.02
upper limit	7.54

Notes:

[30] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 5
Statistical analysis description:	
Change From Baseline at Week 8	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.662 [31]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.29
upper limit	3.41

Notes:

[31] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 4
Statistical analysis description:	
Change From Baseline at Week 6	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.154 [32]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	3.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.25
upper limit	7.5

Notes:

[32] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 3
Statistical analysis description:	
Change From Baseline at Week 6	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg

Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.41 [33]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	1.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.61
upper limit	6.2

Notes:

[33] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
Change From Baseline at Week 4	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.093 [34]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	3.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.56
upper limit	6.95

Notes:

[34] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 13
Statistical analysis description:	
Change From Baseline at Week 16	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.677 [35]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-1.01

Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.98
upper limit	3.95

Notes:

[35] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 12
Statistical analysis description:	
Change From Baseline at Week 14	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.08 [36]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	5.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.67
upper limit	11.06

Notes:

[36] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 11
Statistical analysis description:	
Change From Baseline at Week 14	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.764 [37]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.8
upper limit	5.05

Notes:

[37] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 10

Statistical analysis description:	
Change From Baseline at Week 12	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.158 [38]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	2.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.09
upper limit	6.4

Notes:

[38] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 9
Statistical analysis description:	
Change From Baseline at Week 12	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.909 [39]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-0.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.03
upper limit	3.6

Notes:

[39] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Ststistical Analysis 8
Statistical analysis description:	
Change From Baseline at Week 10	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.039 [40]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	4.93

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.26
upper limit	9.6

Notes:

[40] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 14
Statistical analysis description:	
Change From Baseline at Week 16	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.055 [41]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	4.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.1
upper limit	9.73

Notes:

[41] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 7
Statistical analysis description:	
Change From Baseline at Week 10	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.586 [42]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	1.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.44
upper limit	5.98

Notes:

[42] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Secondary: Change From Baseline in Revised 15-item Myasthenia Gravis Quality of Life Scale (MG-QoL15r) Scale Score

End point title	Change From Baseline in Revised 15-item Myasthenia Gravis Quality of Life Scale (MG-QoL15r) Scale Score

End point description:

A participant-reported score that assesses the participant's perception of impairment and disability and the degree to which the participant tolerates disease manifestations. Each question is graded on a 3-point scale from 0=normal to 2=severe with a total score of 0 to 30; the higher score indicates worse MG disease activity. Negative change indicates improvement. MMRM was used for the analysis. Full Analysis Set included all randomised participants who had baseline and at least 1 post-baseline efficacy assessment. n=Number analysed is the number of participants available for analysis at the specified timepoint.

End point type	Secondary

End point timeframe:

Baseline up to Week 32

End point values	TAK-079 Placebo-matching	TAK-079 300 mg	TAK-079 600 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12	12	12	
Units: score on a scale				
arithmetic mean (standard deviation)				
Change From Baseline at Week 4(n=12,12,12)	-3.1 (± 3.85)	-3.9 (± 4.46)	-3.2 (± 4.43)	
Change From Baseline at Week 6(n=12,11,11)	-4.3 (± 4.11)	-5.8 (± 6.00)	-3.4 (± 3.53)	
Change From Baseline at Week 8(n=12,11,12)	-3.2 (± 4.00)	-5.6 (± 6.53)	-3.3 (± 3.74)	
Change From Baseline at Week 10(n=11,11,11)	-2.5 (± 6.12)	-6.3 (± 6.07)	-3.9 (± 3.70)	
Change From Baseline at Week 12(n=11,11,12)	-2.5 (± 5.32)	-6.1 (± 7.25)	-4.1 (± 4.40)	
Change From Baseline at Week 14(n=11,10,10)	-2.0 (± 7.06)	-6.4 (± 6.98)	-0.9 (± 5.49)	
Change From Baseline at Week 16(n=10,10,10)	-3.8 (± 4.44)	-5.8 (± 6.83)	-2.3 (± 6.43)	
Change From Baseline at Week 20(n=0,8,11)	9999 (± 9999)	-3.3 (± 7.01)	-4.7 (± 5.48)	
Change From Baseline at Week 24(n=0,8,9)	9999 (± 9999)	-7.1 (± 7.95)	-3.8 (± 5.31)	
Change From Baseline at Week 28(n=0,10,8)	9999 (± 9999)	-4.8 (± 10.36)	-4.0 (± 6.16)	
Change From Baseline at Week 32(n=0,9,8)	9999 (± 9999)	-6.2 (± 7.31)	-2.4 (± 4.78)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Change From Baseline at Week 4

Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg

Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.78 [43]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	0.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.23
upper limit	4.27

Notes:

[43] - From a MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 3
Statistical analysis description:	
Change From Baseline at Week 6	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.984 [44]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-0.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.22
upper limit	4.14

Notes:

[44] - From a MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 4
Statistical analysis description:	
Change From Baseline at Week 6	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.213 [45]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	2.44

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.47
upper limit	6.35

Notes:

[45] - From a MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 5
Statistical analysis description:	
Change From Baseline at Week 8	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.371 [46]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-1.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.4
upper limit	2.45

Notes:

[46] - From a MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 6
Statistical analysis description:	
Change From Baseline at Week 8	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.956 [47]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	0.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.01
upper limit	4.23

Notes:

[47] - From a MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:	
Change From Baseline at Week 4	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.771 [48]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.99
upper limit	3.99

Notes:

[48] - From a MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 7
Statistical analysis description:	
Change From Baseline at Week 10	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.641 [49]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.65
upper limit	3.53

Notes:

[49] - From a MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 11
Statistical analysis description:	
Change From Baseline at Week 14	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.699 [50]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-1.14

Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.07
upper limit	4.8

Notes:

[50] - From a MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 10
Statistical analysis description:	
Change From Baseline at Week 12	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.769 [51]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-0.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.37
upper limit	4

Notes:

[51] - From a MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 8
Statistical analysis description:	
Change From Baseline at Week 10	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.876 [52]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-0.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.61
upper limit	3.95

Notes:

[52] - From a MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 9

Statistical analysis description:	
Change From Baseline at Week 12	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.458 [53]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-1.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.91
upper limit	3.18

Notes:

[53] - From a MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 13
Statistical analysis description:	
Change From Baseline at Week 16	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.944 [54]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.55
upper limit	5.95

Notes:

[54] - From a MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 12
Statistical analysis description:	
Change From Baseline at Week 14	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.687 [55]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	1.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.41
upper limit	6.62

Notes:

[55] - From a MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 14
Statistical analysis description:	
Change From Baseline at Week 16	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.351 [56]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	2.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.87
upper limit	7.83

Notes:

[56] - From a MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Secondary: Change From Baseline in Anti-acetylcholine Receptor (AChR) Antibody Levels

End point title	Change From Baseline in Anti-acetylcholine Receptor (AChR) Antibody Levels

End point description:

Clinical laboratory evaluations of anti-AChR antibodies were tested to monitor disease activity. MMRM was used for the analysis. Full Analysis Set included all randomised participants who had baseline and at least 1 post-baseline efficacy assessment. Subjects analysed is the number of participants available for analyses. n=Number analysed is the number of participants available for analysis at the specified timepoint. 9999=Data not reported for 0 participants.

End point type	Secondary

End point timeframe:

Baseline up to Week 32

End point values	TAK-079 Placebo-matching	TAK-079 300 mg	TAK-079 600 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	11	10	12	
Units: nmol/L				
arithmetic mean (standard deviation)				

Change From Baseline at Week 2(n=11,10,12)	-6.300 (± 25.3514)	-19.452 (± 50.5551)	-3.450 (± 5.7767)	
Change From Baseline at Week 3(n=11,10,12)	-3.989 (± 22.9732)	-14.821 (± 44.4776)	-2.509 (± 17.5221)	
Change From Baseline at Week 4(n=11,10,12)	-0.976 (± 11.7759)	-24.253 (± 51.2627)	-13.680 (± 87.1669)	
Change From Baseline at Week 5(n=11,10,12)	-8.199 (± 13.9571)	-32.251 (± 58.3701)	-9.831 (± 26.2188)	
Change From Baseline at Week 6(n=11,9,11)	-19.152 (± 49.2221)	-27.518 (± 52.6672)	-2.148 (± 23.2543)	
Change From Baseline at Week 7(n=11,9,11)	-11.235 (± 26.2159)	-33.261 (± 56.3495)	-9.882 (± 16.2972)	
Change From Baseline at Week 8(n=10,9,12)	-7.731 (± 27.8994)	-39.386 (± 72.3110)	-5.668 (± 10.4493)	
Change From Baseline at Week 10(n=10,9,11)	-37.473 (± 120.9186)	-37.083 (± 60.8092)	-6.654 (± 7.8236)	
Change From Baseline at Week 12(n=10,9,12)	-0.832 (± 31.0318)	-38.430 (± 64.4594)	-7.827 (± 11.2120)	
Change From Baseline at Week 14(n=9,8,10)	-12.729 (± 49.8823)	-40.771 (± 74.3624)	-8.058 (± 15.8407)	
Change From Baseline at Week 16(n=7,8,10)	-3.501 (± 9.8729)	-49.843 (± 77.6316)	-4.909 (± 8.8478)	
Change From Baseline at Week 20(n=0,7,11)	9999 (± 9999)	-52.217 (± 83.1537)	-4.378 (± 7.7297)	
Change From Baseline at Week 24(n=0,7,9)	9999 (± 9999)	-43.079 (± 77.4438)	-4.802 (± 10.5639)	
Change From Baseline at Week 28(n=0,8,9)	9999 (± 9999)	-73.786 (± 111.0044)	-6.044 (± 11.3755)	
Change From Baseline at Week 32(n=0,7,8)	9999 (± 9999)	-51.296 (± 67.3437)	-5.485 (± 11.8380)	

Statistical analyses

Statistical analysis title	Statistical Analysis 2
Statistical analysis description: Change From Baseline at Week 2	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.328 [57]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-15.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	-47.5
upper limit	15.96

Notes:

[57] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:	
Change From Baseline at Week 2	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.09 [58]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-27.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-60.18
upper limit	4.38

Notes:

[58] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 3
Statistical analysis description:	
Change From Baseline at Week 3	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.441 [59]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-12.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	-44.94
upper limit	19.63

Notes:

[59] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 4
Statistical analysis description:	
Change From Baseline at Week 3	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.931 [60]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	1.39

Confidence interval	
level	95 %
sides	2-sided
lower limit	-30.33
upper limit	33.12

Notes:

[60] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 5
Statistical analysis description:	
Change From Baseline at Week 4	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.087 [61]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-28.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-60.46
upper limit	4.11

Notes:

[61] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 6
Statistical analysis description:	
Change From Baseline at Week 4	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.783 [62]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	4.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	-27.29
upper limit	36.16

Notes:

[62] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 7

Statistical analysis description:	
Change From Baseline at Week 5	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.077 [63]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-29.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-61.36
upper limit	3.21

Notes:

[63] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 10
Statistical analysis description:	
Change From Baseline at Week 6	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 1 [64]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-32.18
upper limit	32.19

Notes:

[64] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 9
Statistical analysis description:	
Change From Baseline at Week 6	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4 [65]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-14.14

Confidence interval	
level	95 %
sides	2-sided
lower limit	-47.19
upper limit	18.91

Notes:

[65] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 8
Statistical analysis description:	
Change From Baseline at Week 5	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.33 [66]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-15.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	-47.45
upper limit	16

Notes:

[66] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 11
Statistical analysis description:	
Change From Baseline at Week 7	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.117 [67]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-26.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	-59.64
upper limit	6.69

Notes:

[67] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 15

Statistical analysis description:	
Change From Baseline at Week 10	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.815 [68]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-3.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	-37.34
upper limit	29.4

Notes:

[68] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 14
Statistical analysis description:	
Change From Baseline at Week 8	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.215 [69]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-20.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	-52.92
upper limit	11.95

Notes:

[69] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 13
Statistical analysis description:	
Change From Baseline at Week 8	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.005 [70]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-47.91

Confidence interval	
level	95 %
sides	2-sided
lower limit	-81.54
upper limit	-14.29

Notes:

[70] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 12
Statistical analysis description:	
Change From Baseline at Week 7	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.436 [71]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-12.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	-44.94
upper limit	19.44

Notes:

[71] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 16
Statistical analysis description:	
Change From Baseline at Week 10	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.794 [72]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-4.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	-36.84
upper limit	28.22

Notes:

[72] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 12

Statistical analysis description:	
Change From Baseline at Week 12	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.033 [73]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-36.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	-70.48
upper limit	-3.08

Notes:

[73] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 21
Statistical analysis description:	
Week 16	
Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001 [74]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-62.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	-100.64
upper limit	-25.31

Notes:

[74] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 20
Statistical analysis description:	
Week 14	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.036 [75]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-36.94

Confidence interval	
level	95 %
sides	2-sided
lower limit	-71.39
upper limit	-2.48

Notes:

[75] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 19

Statistical analysis description:

Week 14

Comparison groups	TAK-079 Placebo-matching v TAK-079 300 mg
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002 [76]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-56.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-91.69
upper limit	-20.73

Notes:

[76] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 18

Statistical analysis description:

Week 12

Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.513 [77]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-10.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	-43.26
upper limit	21.67

Notes:

[77] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Statistical analysis title	Statistical Analysis 22

Statistical analysis description:	
Week 16	
Comparison groups	TAK-079 Placebo-matching v TAK-079 600 mg
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.13 [78]
Method	MMRM
Parameter estimate	Difference in LS Mean
Point estimate	-28.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	-66.12
upper limit	8.51

Notes:

[78] - From MMRM analysis over all post-baseline visits, with the change from baseline as the outcome, treatment group, visit, and treatment-by-visit interaction as factors, and adjusted by baseline value and baseline-by-visit interaction.

Secondary: Change From Baseline in Anti- Muscle-specific Tyrosine Kinase (MuSK) Titer Levels

End point title	Change From Baseline in Anti- Muscle-specific Tyrosine Kinase (MuSK) Titer Levels

End point description:

Clinical laboratory evaluations of anti-MuSK antibodies were tested to monitor disease activity. Data is reported for participants who were positive for anti-MuSK antibodies at baseline. Full Analysis Set included all randomised participants who had baseline and at least 1 post-baseline efficacy assessment. Subjects analysed is the number of participants available for analyses. n=Number analysed is the number of participants available for analysis at the specified timepoint. 99999=SD was not estimable for 1 participant. 9999=Data was not reported for 0 participants.

End point type	Secondary

End point timeframe:

Baseline up to Week 32

End point values	TAK-079 Placebo-matching	TAK-079 300 mg	TAK-079 600 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1	2	0[79]	
Units: titer				
arithmetic mean (standard deviation)				
Change From Baseline at Week 2(n=1,2,0)	0.0 (± 99999)	-160.0 (± 226.27)	()	
Change From Baseline at Week 3(n=1,2,0)	0.0 (± 99999)	-200.0 (± 169.71)	()	
Change From Baseline at Week 4(n=1,2,0)	0.0 (± 99999)	-240.0 (± 339.41)	()	
Change From Baseline at Week 5(n=1,2,0)	0.0 (± 99999)	-240.0 (± 339.41)	()	
Change From Baseline at Week 6(n=1,2,0)	0.0 (± 99999)	-240.0 (± 339.41)	()	
Change From Baseline at Week 7(n=1,2,0)	0.0 (± 99999)	-240.0 (± 339.41)	()	

Change From Baseline at Week 8(n=1,2,0)	0.0 (± 99999)	-280.0 (± 395.98)	()	
Change From Baseline at Week 10(n=1,2,0)	0.0 (± 99999)	-280.0 (± 395.98)	()	
Change From Baseline at Week 12(n=1,2,0)	0.0 (± 99999)	-300.0 (± 424.26)	()	
Change From Baseline at Week 14(n=1,2,0)	0.0 (± 99999)	-300.0 (± 424.26)	()	
Change From Baseline at Week 16(n=1,2,0)	0.0 (± 99999)	-300.0 (± 424.26)	()	
Change From Baseline at Week 20(n=0,1,0)	9999 (± 9999)	0.0 (± 99999)	()	
Change From Baseline at Week 24(n=0,2,0)	9999 (± 9999)	-310.0 (± 438.41)	()	
Change From Baseline at Week 28(n=0,2,0)	9999 (± 9999)	-310.0 (± 438.41)	()	
Change From Baseline at Week 32(n=0,2,0)	9999 (± 9999)	-310.0 (± 438.41)	()	

Notes:

[79] - Data was not analyzed of this arm group.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With 2-point Reduction in MG-ADL Total Score

End point title	Percentage of Participants With 2-point Reduction in MG-ADL Total Score

End point description:

The percentage of responders with at least a 2-point reduction in MG-ADL total score from baseline is reported. MG-ADL is a participant-reported scale to assess MG symptoms to evaluate capacity to perform activities of daily living. Each question is graded on a 4-point scale from 0=normal to 3=severe with a total score of 0 to 24; the higher score indicates greater functional impairment and disability. Percentages are rounded off to whole number at the nearest decimal. Full Analysis Set included all randomised participants who had baseline and at least 1 post-baseline efficacy assessment.

End point type	Secondary

End point timeframe:

At Weeks 4, 6, 8, 10, 12, 14, 16, 20, 24, 28 and 32

End point values	TAK-079 Placebo-matching	TAK-079 300 mg	TAK-079 600 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12	12	12	
Units: percentage of participants				
number (not applicable)				
Week 4	50.00	75.00	58.33	
Week 6	91.67	75.00	58.33	
Week 8	83.33	66.67	66.67	
Week 10	83.33	83.33	50.00	
Week 12	75.00	75.00	50.00	
Week 14	66.67	75.00	50.00	
Week 16	66.67	66.67	33.33	

Week 20	0.0	66.67	58.33	
Week 24	0.0	58.33	58.33	
Week 28	0.0	58.33	58.33	
Week 32	0.0	41.67	41.67	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With 3-point Reduction in QMG Total Score

End point title	Percentage of Participants With 3-point Reduction in QMG Total Score

End point description:

The percentage of responders with at least a 3-point reduction in QMG total score from baseline is reported. QMG is a physician-reported scale to assess MG disease severity by quantifying several body functions by physical exam. Each question is graded on a 4-point scale from 0=normal to 3=severe with a total score of 0 to 39; the higher score indicates greater disease burden. Percentages are rounded off to whole number at the nearest decimal. Full Analysis Set included all randomised participants who had baseline and at least 1 post-baseline efficacy assessment.

End point type	Secondary

End point timeframe:

At Weeks 4, 6, 8, 10, 12, 14, 16, 20, 24, 28 and 32

End point values	TAK-079 Placebo-matching	TAK-079 300 mg	TAK-079 600 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12	12	12	
Units: percentage of participants				
number (not applicable)				
Week 4	25.00	50.00	16.67	
Week 6	16.67	41.67	33.33	
Week 8	33.33	66.67	33.33	
Week 10	33.33	66.67	33.33	
Week 12	41.67	75.00	25.00	
Week 14	33.33	66.67	25.00	
Week 16	33.33	58.33	33.33	
Week 20	0.0	41.67	33.33	
Week 24	0.0	41.67	33.33	
Week 28	0.0	41.67	25.00	
Week 32	0.0	16.67	16.67	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With 3-point Reduction in MGC Total Score

End point title	Percentage of Participants With 3-point Reduction in MGC Total Score

End point description:

The percentage of responders with at least a 3-point reduction in MGC total score from baseline is reported. MGC is an assessment scale of MG disease activity based on a combination of participant- and physician-reported items. Each question is graded on 4 levels of impact from normal to severe with a total score of 0 to 50; the higher score indicates worse MG disease activity. Percentages are rounded off to whole number at the nearest decimal. Full Analysis Set included all randomised participants who had baseline and at least 1 post-baseline efficacy assessment.

End point type	Secondary

End point timeframe:

At Weeks 4, 6, 8, 10, 12, 14, 16, 20, 24, 28 and 32

End point values	TAK-079 Placebo-matching	TAK-079 300 mg	TAK-079 600 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12	12	12	
Units: percentage of participants				
number (not applicable)				
Week 4	66.67	75.00	41.67	
Week 6	83.33	66.67	58.33	
Week 8	83.33	83.33	58.33	
Week 10	83.33	75.00	50.00	
Week 12	75.00	91.67	58.33	
Week 14	66.67	83.33	50.00	
Week 16	66.67	75.00	41.67	
Week 20	0.0	75.00	58.33	
Week 24	0.0	66.67	50.00	
Week 28	0.0	58.33	50.00	
Week 32	0.0	41.67	25.00	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From signing the informed consent form up to end of long-term follow-up (up to Week 32)

Adverse event reporting additional description:

At each visit the investigator had to document any occurrence of adverse events and abnormal laboratory findings. Any event spontaneously reported by the participant or observed by the investigator was recorded, irrespective of the relation to study treatment. Safety Analysis Set included participants who received at least 1 dose of study drug.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.0

Reporting groups

Reporting group title	TAK-079 Placebo-matching

Reporting group description:

TAK-079 placebo-matching injection, SC, once weekly in combination with standard background therapy for 8 weeks.

Reporting group title	TAK-079 600 mg

Reporting group description:

TAK-079 600 mg injection, SC, once weekly in combination with standard background therapy for 8 weeks.

Reporting group title	TAK-079 300 mg

Reporting group description:

TAK-079 300 mg injection, SC, once weekly in combination with standard background therapy for 8 weeks.

Serious adverse events	TAK-079 Placebo-matching	TAK-079 600 mg	TAK-079 300 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	1 / 12 (8.33%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Nervous system disorders			
Myasthenia gravis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Enteritis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Psychiatric disorders			
Suicidal ideation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	TAK-079 Placebo-matching	TAK-079 600 mg	TAK-079 300 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 12 (66.67%)	11 / 12 (91.67%)	9 / 12 (75.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Haematoma			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Hypertension			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	3	1	0
Feeling cold			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Fatigue			

subjects affected / exposed	0 / 12 (0.00%)	2 / 12 (16.67%)	1 / 12 (8.33%)
occurrences (all)	0	3	1
Early satiety			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Chills			
subjects affected / exposed	0 / 12 (0.00%)	3 / 12 (25.00%)	0 / 12 (0.00%)
occurrences (all)	0	3	0
Chest discomfort			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Feeling hot			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Injection site bruising			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Injection site haematoma			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Injection site hypertrophy			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	1 / 12 (8.33%)	3 / 12 (25.00%)	2 / 12 (16.67%)
occurrences (all)	1	3	3
Malaise			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Injection site pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	5
Immune system disorders			

Immunisation reaction			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea exertional			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Oropharyngeal pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Blood glucose increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Blood immunoglobulin A decreased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
SARS-CoV-2 test positive			

subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Staphylococcus test positive			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Limb injury			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Atrioventricular block first degree			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Dysarthria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Hypoaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Myasthenia gravis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Parosmia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Tension headache			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Thrombocytosis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Normochromic normocytic anaemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Lymphopenia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Periorbital oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Conjunctivitis allergic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Diplopia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Ocular hypertension			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Angle closure glaucoma			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Vitreous detachment			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Visual impairment			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Gastrointestinal disorders			

Vomiting			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Odynophagia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Rash papular			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Renal and urinary disorders			
Urine odour abnormal			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Muscular weakness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Pain in jaw			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Joint noise			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0

Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Abdominal wall abscess			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Bartholin's abscess			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Cellulitis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 12 (8.33%)	2 / 12 (16.67%)	0 / 12 (0.00%)
occurrences (all)	2	2	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
04 March 2020	Following changes were implemented with Protocol Amendment 2: -Updated inclusion criterion to clarify the intent to exclude only pulse steroid therapy. Dosing of corticosteroids with oral therapy every other day to be as acceptable as daily. -Updated exclusion criterion to exclude only those receiving live vaccines and not inactive vaccines. -Updated exclusion criterion to clarify the intent not to exclude a minor, benign, resolved, localized herpes simplex infection not requiring systemic therapy. -Updated exclusion criterion to change "lower limit of normal" to "5 g/L." As a result of this edit, participants were excluded if the IgG was less than 5 g/L (500 mg/dL) at screening. -Updated exclusion criterion to clarify the intent to exclude participants with active hepatitis C and not those who have been fully cured of the disease. Additionally, more stringent criteria were used to exclude participants with hepatitis B infection. -Updated the SAE reporting procedure to include an acknowledgement of receipt. -Added a global fax number to the SAE Reporting Contact Information. -Descriptors for circulating biomarker samples and quantitative immunoglobulin (Ig) A/IgM/IgG samples were changed from blood to serum. -Updated the version number of the QMG scoring assessment tool, which fixed a typographical error in the definition of severe forced vital capacity (FVC). -Serum samples for hepatitis B, hepatitis C, and human immunodeficiency virus (HIV) were added to Primary Specimen Collection Table. -Added serum pregnancy test at Week 32. -Eligibility criteria regarding immunosuppressive drugs now required a stable dose for at least 3 months before screening. Stable dosing of azathioprine remained at 6 months prior to screening.
28 September 2020	Following changes were implemented with Protocol Amendment 3: Added contingency plans for the COVID-19 pandemic by incorporating flexibility for the study participants and investigators, while continuing to maintain participant safety and study integrity as per local site regulations.
01 February 2021	Following changes were implemented with Protocol Amendment 4: Clarified the intent of exclusion criterion.
05 May 2021	Following changes were implemented with Protocol Amendment 5: Changed the legal entity name for the sponsor to Takeda Development Center Americas, Inc., 95 Hayden Avenue, Lexington, MA 02421, USA.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported