Clinical trial results:
An open-label, crossover study to evaluate rozanolixizumab self-administration by study participants with generalized Myasthenia Gravis

Summary

EudraCT number	2022-003870-21
Trial protocol	IT ES
Global end of trial date	23 April 2024

Results information

Result version number	v1 (current)
This version publication date	07 May 2025
First version publication date	07 May 2025

Trial information

Trial identification

Sponsor protocol code	MG0020

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05681715
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	UCB Biopharma SRL
Sponsor organisation address	Allée de la Recherche 60, Brussels, Belgium, 1070
Public contact	Clin Trial Reg & Results Disclosure, UCB BIOSCIENCES GmbH, clinicaltrials@ucb.com
Scientific contact	Clin Trial Reg & Results Disclosure, UCB BIOSCIENCES GmbH, clinicaltrials@ucb.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	10 May 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	23 April 2024
Global end of trial reached?	Yes
Global end of trial date	23 April 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the ability of study participants with generalized Myasthenia Gravis (gMG) to successfully self-administer rozanolixizumab after training in the self-administration technique using the syringe driver and manual push methods.

Protection of trial subjects:

During the conduct of the study all participants were closely monitored.

Background therapy:

Background therapy as permitted in the protocol

Evidence for comparator:

Not applicable

Actual start date of recruitment	17 April 2023
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 5
Country: Number of subjects enrolled	Georgia: 6
Country: Number of subjects enrolled	Germany: 5
Country: Number of subjects enrolled	Italy: 8
Country: Number of subjects enrolled	Japan: 4
Country: Number of subjects enrolled	Poland: 15
Country: Number of subjects enrolled	Serbia: 2
Country: Number of subjects enrolled	Spain: 4
Country: Number of subjects enrolled	United Kingdom: 3
Country: Number of subjects enrolled	United States: 10
Worldwide total number of subjects	62
EEA total number of subjects	32

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
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)	45
From 65 to 84 years	17
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study started to enroll participants in April 2023 and concluded in April 2024.

Pre-assignment

Screening details:

Participant Flow refers to Safety Set (SS) for Training Period and Randomized Safety Set (RSS) for Self-administration Periods 1 and 2.

Period 1

Period 1 title	Training Period (6-weeks)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	All Participants: Training Period

Arm description:

All participants received weekly doses of subcutaneous rozanolixizumab (RLZ) as per their body weight. During the Training Period, the study participants were trained by healthcare professionals on the subcutaneous self-administration of RLZ using both the Syringe Driver (SRD) and Manual Push (MP) methods for 6 weeks before randomization.

Arm type	Experimental
Investigational medicinal product name	Rozanolixizumab
Investigational medicinal product code	UCB7665
Other name	RLZ
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received RLZ with syringe driver or manual push at pre-specified time-points.

Number of subjects in period 1	All Participants: Training Period
Started	62
Completed	55
Not completed	7
Consent withdrawn by participant (not due to AE)	1
Adverse event, non-fatal	3
Not Eligible for SA but continued in study	3

Period 2

Period 2 title	Self-administration Period 1 (6 Weeks)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Sequence 1: RLZ Syringe driver (SRD) – RLZ Manual Push (MP)

Arm description:

Randomized participants Self-administered RLZ dose subcutaneously as per their body weight with SRD once every week from Week 7 to 12 during Self-administration Period 1 followed by RLZ administered subcutaneously with MP once every week from Week 13 to 18 during Self-administration Period 2. Study has no wash-out period.

Arm type	Experimental
Investigational medicinal product name	Rozanolixizumab
Investigational medicinal product code	UCB7665
Other name	RLZ
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received RLZ with syringe driver or manual push at pre-specified time-points.

Arm title	Sequence 2: RLZ MP – RLZ SRD

Arm description:

Randomized participants Self-administered RLZ dose subcutaneously as per their body weight with MP once every week from Week 7 to 12 during Self-administration Period 1 followed by RLZ administered subcutaneously with SRD once every week from Week 13 to 18 during Self-administration Period 2. Study had no wash-out period.

Arm type	Experimental
Investigational medicinal product name	Rozanolixizumab
Investigational medicinal product code	UCB7665
Other name	RLZ
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received RLZ with syringe driver or manual push at pre-specified time-points.

Number of subjects in period 2	Sequence 1: RLZ Syringe driver (SRD) – RLZ Manual Push (MP)	Sequence 2: RLZ MP – RLZ SRD
Started	28	27
Completed	23	26
Not completed	5	1
Participant became ineligible for SA	1	-
Consent withdrawn by participant (not due to AE)	-	1
Adverse event, non-fatal	1	-
Diagnosis change to amyotrophic lateral sclerosis	1	-

Missed infusion at Visit 13, SA Period1 incomplete	2	-

Period 3

Period 3 title	Self-administration Period 2 (6 Weeks)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Sequence 1: RLZ SRD – RLZ MP

Arm description:

Randomized participants Self-administered RLZ dose subcutaneously as per their body weight with SRD once every week from Week 7 to 12 during Self-administration Period 1 followed by RLZ administered subcutaneously with MP once every week from Week 13 to 18 during Self-administration Period 2. Study has no wash-out period.

Arm type	Experimental
Investigational medicinal product name	Rozanolixizumab
Investigational medicinal product code	UCB7665
Other name	RLZ
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received RLZ with syringe driver or manual push at pre-specified time-points.

Arm title	Sequence 2: RLZ MP – RLZ SRD

Arm description:

Randomized participants Self-administered RLZ dose subcutaneously as per their body weight with MP once every week from Week 7 to 12 during Self-administration Period 1 followed by RLZ administered subcutaneously with SRD once every week from Week 13 to 18 during Self-administration Period 2. Study had no wash-out period.

Arm type	Experimental
Investigational medicinal product name	Rozanolixizumab
Investigational medicinal product code	UCB7665
Other name	RLZ
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received RLZ with syringe driver or manual push at pre-specified time-points.

Number of subjects in period 3	Sequence 1: RLZ SRD – RLZ MP	Sequence 2: RLZ MP – RLZ SRD
Started	23	26
Missed V13 at P1, continued P2	2 [1]	0 [2]
Completed	23	26

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Two participants missed Visit 13 (Week 12) during Period 1, so were not counted as having completed Period 1. Both participants continued into Period 2.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Two participants missed Visit 13 (Week 12) during Period 1, so were not counted as having completed Period 1. Both participants continued into Period 2.

Baseline characteristics

Reporting groups	
Reporting group title	All Participants: Training Period
Reporting group description:	
All participants received weekly doses of subcutaneous rozanolixizumab (RLZ) as per their body weight. During the Training Period, the study participants were trained by healthcare professionals on the subcutaneous self-administration of RLZ using both the Syringe Driver (SRD) and Manual Push (MP) methods for 6 weeks before randomization.	

Reporting group values	All Participants: Training Period	Total	
Number of subjects	62	62	
Age Categorical Units: participants			
18 - <65 years	45	45	
65 - <85 years	17	17	
>=85 years	0	0	
Age Continuous Units: years			
arithmetic mean	53.3		
standard deviation	± 15.7	-	
Sex: Female, Male Units: participants			
Female	35	35	
Male	27	27	

End points

End points reporting groups

Reporting group title	All Participants: Training Period

Reporting group description:

All participants received weekly doses of subcutaneous rozanolixizumab (RLZ) as per their body weight. During the Training Period, the study participants were trained by healthcare professionals on the subcutaneous self-administration of RLZ using both the Syringe Driver (SRD) and Manual Push (MP) methods for 6 weeks before randomization.

Reporting group title	Sequence 1: RLZ Syringe driver (SRD) – RLZ Manual Push (MP)

Reporting group description:

Randomized participants Self-administered RLZ dose subcutaneously as per their body weight with SRD once every week from Week 7 to 12 during Self-administration Period 1 followed by RLZ administered subcutaneously with MP once every week from Week 13 to 18 during Self-administration Period 2. Study has no wash-out period.

Reporting group title	Sequence 2: RLZ MP – RLZ SRD

Reporting group description:

Randomized participants Self-administered RLZ dose subcutaneously as per their body weight with MP once every week from Week 7 to 12 during Self-administration Period 1 followed by RLZ administered subcutaneously with SRD once every week from Week 13 to 18 during Self-administration Period 2. Study had no wash-out period.

Reporting group title	Sequence 1: RLZ SRD – RLZ MP

Reporting group description:

Randomized participants Self-administered RLZ dose subcutaneously as per their body weight with SRD once every week from Week 7 to 12 during Self-administration Period 1 followed by RLZ administered subcutaneously with MP once every week from Week 13 to 18 during Self-administration Period 2. Study has no wash-out period.

Reporting group title	Sequence 2: RLZ MP – RLZ SRD

Reporting group description:

Randomized participants Self-administered RLZ dose subcutaneously as per their body weight with MP once every week from Week 7 to 12 during Self-administration Period 1 followed by RLZ administered subcutaneously with SRD once every week from Week 13 to 18 during Self-administration Period 2. Study had no wash-out period.

Subject analysis set title	All Participants: Training Period
Subject analysis set type	Safety analysis

Subject analysis set description:

All participants received weekly doses of rozanolixizumab (RLZ) as per their body weight administered subcutaneously with Manual push (MP) and/or Syringe driver (SRD) with the guidance of healthcare professional or Self-administered to practice both methods of administration during this Training Period for 6 weeks before randomization.

Subject analysis set title	Period 1: RLZ SRD
Subject analysis set type	Full analysis

Subject analysis set description:

Randomized participants Self-administered RLZ dose subcutaneously as per their body weight with SRD once every week from Week 7 to 12 during Self-administration Period 1.

Subject analysis set title	Period 1: RLZ MP
Subject analysis set type	Full analysis

Subject analysis set description:

Randomized participants Self-administered RLZ dose subcutaneously as per their body weight with MP once every week from Week 7 to 12 during Self-administration Period 1.

Subject analysis set title	Period 2: RLZ SRD
Subject analysis set type	Full analysis

Subject analysis set description:

Randomized participants Self-administered RLZ dose subcutaneously as per their body weight with SRD once every week from Week 13 to 18 during Self-administration Period 2.

Subject analysis set title	Period 2: RLZ MP
Subject analysis set type	Full analysis

Subject analysis set description:

Randomized participants Self-administered RLZ dose subcutaneously as per their body weight with MP once every week from Week 13 to 18 during Self-administration Period 2.

Subject analysis set title	Period 1: RLZ SRD
Subject analysis set type	Safety analysis

Subject analysis set description:

Randomized participants Self-administered RLZ dose subcutaneously as per their body weight with SRD once every week from Week 7 to 12 during Self-administration Period 1.

Subject analysis set title	Period 1: RLZ MP
Subject analysis set type	Safety analysis

Subject analysis set description:

Randomized participants Self-administered RLZ dose subcutaneously as per their body weight with MP once every week from Week 7 to 12 during Self-administration Period 1.

Subject analysis set title	Period 2: RLZ SRD
Subject analysis set type	Safety analysis

Subject analysis set description:

Randomized participants Self-administered RLZ dose subcutaneously as per their body weight with SRD once every week from Week 13 to 18 during Self-administration Period 2.

Subject analysis set title	Period 2: RLZ MP
Subject analysis set type	Safety analysis

Subject analysis set description:

Randomized participants Self-administered RLZ dose subcutaneously as per their body weight with MP once every week from Week 13 to 18 during Self-administration Period 2.

Subject analysis set title	RLZ Total
Subject analysis set type	Safety analysis

Subject analysis set description:

All study participants who received at least 1 dose of RLZ subcutaneously once every week with SRD or MP in Training Period, SA Period 1 and SA Period 2 for 18 weeks.

Primary: Percentage of participants with Successful Self-administration of rozanolixizumab (with correct use of syringe driver and manual push, respectively) during the Self-administration Period at Visit 13 (Week 12)

End point title	Percentage of participants with Successful Self-administration of rozanolixizumab (with correct use of syringe driver and manual push, respectively) during the Self-administration Period at Visit 13 (Week 12)[1]

End point description:

Successful Self-administration was defined by the participant (i) choosing the correct infusion site, (ii) administering SC, and (iii) delivering the intended dose. The Full Analysis Set (FAS) consisted of all participants who were included in SS, were randomized, and completed both Self-administration periods, in accordance with the randomization scheme.

End point type	Primary

End point timeframe:

Week 12 (last dose of Self-administration Period 1)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was planned for this study. Results were summarized as descriptive statistics only.

End point values	Period 1: RLZ SRD	Period 1: RLZ MP		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	18	23		
Units: percentage of participants				
number (not applicable)	100	100		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of participants with Successful Self-administration of rozanolixizumab (with correct use of syringe driver and manual push, respectively) during the Self-administration Period at Visit 19 (Week 18)

End point title	Percentage of participants with Successful Self-administration of rozanolixizumab (with correct use of syringe driver and manual push, respectively) during the Self-administration Period at Visit 19 (Week 18)[2]

End point description:

Successful Self-administration was defined by the participant (i) choosing the correct infusion site, (ii) administering SC, and (iii) delivering the intended dose. The FAS consisted of all participants who were included in SS, were randomized, and completed both Self-administration periods, in accordance with the randomization scheme.

End point type	Primary

End point timeframe:

Week 18 (last dose of Self-administration Period 2)

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was planned for this study. Results were summarized as descriptive statistics only.

End point values	Period 2: RLZ SRD	Period 2: RLZ MP		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	23	18		
Units: percentage of participants				
number (not applicable)	100	100		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with Treatment-Emergent Adverse Events (TEAEs) after syringe driver or manual push Self-administration from Visit 2 (Week 1) up to the End of Study Visit (Visit 21 [Week 26])

End point title	Percentage of participants with Treatment-Emergent Adverse Events (TEAEs) after syringe driver or manual push Self-administration from Visit 2 (Week 1) up to the End of Study Visit (Visit 21 [Week 26])

End point description:

An Adverse Event (AE) was any untoward medical occurrence in a patient or clinical investigation participant administered a pharmaceutical product, which did not necessarily have a causal relationship with this treatment. An AE could therefore be any unfavorable and unintended sign, symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not

related to the medicinal (investigational) product. A TEAE was defined as an AE starting on or after the date of first administration of rozanolixizumab in the study, up to and including 8 weeks (56 days) after the final dose. SS included all study participants who received at least 1 dose of investigational medicinal product (partial or full). Randomized safety set (RSS) consisted of all participants who are included in SS and were randomized. Here, 'Number of Participants Analyzed' included those participants who were evaluable for the outcome measure.

End point type	Secondary

End point timeframe:

From Week 1 up to the End of Study Visit (Week 26)

End point values	Period 1: RLZ SRD	Period 1: RLZ MP	Period 2: RLZ SRD	Period 2: RLZ MP
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	28	27	26	26
Units: percentage of participants				
number (not applicable)	35.7	29.6	26.9	38.5

End point values	RLZ Total			
Subject group type	Subject analysis set			
Number of subjects analysed	62			
Units: percentage of participants				
number (not applicable)	75.8			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with local site reactions up to 24 hours after each administration during the Training Period and Self-administration Periods

End point title	Percentage of participants with local site reactions up to 24 hours after each administration during the Training Period and Self-administration Periods

End point description:

The local site reactions up to 24 hours after each administration are defined as AEs reported as local site reactions as per case report form within one day after RLZ administration. SS included all study participants who received at least 1 dose of IMP (partial or full). Here, 'Number of Participants Analyzed' included those participants who were evaluable for the outcome measure.

End point type	Secondary

End point timeframe:

Up to 24 hours after each administration during the Training Period (Baseline to Week 6) and Self-administration Periods (Week 7 to Week 18)

End point values	All Participants: Training Period	Period 1: RLZ SRD	Period 1: RLZ MP	Period 2: RLZ SRD
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	62	28	27	26
Units: percentage of participants				
number (not applicable)	0	0	0	0

End point values	Period 2: RLZ MP			
Subject group type	Subject analysis set			
Number of subjects analysed	26			
Units: percentage of participants				
number (not applicable)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with medication errors associated with adverse reactions during the 2 Self-administration Periods of the study

End point title	Percentage of participants with medication errors associated with adverse reactions during the 2 Self-administration Periods of the study

End point description:

Medication errors were defined as an unintended failure in the drug treatment process that leads to, or has the potential to lead to, harm to the study participant. Medication Errors associated with adverse reactions during the 2 Self-administration Periods were measured. RSS consisted of all participants who are included in SS and were randomized. Here, 'Number of Participants Analyzed' included those participants who were evaluable for the outcome measure.

End point type	Secondary

End point timeframe:

During the Self-administration Periods (Week 7 to Week 18)

End point values	Period 1: RLZ SRD	Period 1: RLZ MP	Period 2: RLZ SRD	Period 2: RLZ MP
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	28	27	26	26
Units: percentage of participants				
number (not applicable)	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From Week 1 up to the End of Study Visit (Week 26)

Adverse event reporting additional description:

TEAEs were reported for SS and RSS. The RLZ Total arm included data for all 62 participants from the Training Period to the Safety Follow-Up Period including participants who discontinued during the Training Period or were not randomized but continued in the study.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.0

Reporting groups

Reporting group title	All Participants: Training Period

Reporting group description:

All participants received weekly doses of subcutaneous rozanolixizumab (RLZ) as per their body weight. During the Training Period, the study participants were trained by healthcare professionals on the subcutaneous self-administration of RLZ using both the Syringe Driver (SRD) and Manual Push (MP) methods for 6 weeks before randomization.

Reporting group title	RLZ Total

Reporting group description:

All study participants who received at least 1 dose of RLZ subcutaneously once every week with SRD or MP in Training Period, SA Period 1 and SA Period 2 for 18 weeks.

Reporting group title	Self-Administration Period 1 and 2: RLZ MP

Reporting group description:

Randomized participants self administered RLZ dose subcutaneously as per their body weight with MP once every week from Week 7 to 12 during Self-administration Period 1 followed by RLZ administered subcutaneously with SRD once every week from Week 13 to 18 during Self-administration Period 2. Study had no wash-out period.

Reporting group title	Self-Administration Period 1 and 2: RLZ SRD

Reporting group description:

Randomized participants self administered RLZ dose subcutaneously as per their body weight with SRD once every week from Week 7 to 12 during Self-administration Period 1 followed by RLZ administered subcutaneously with MP once every week from Week 13 to 18 during Self-administration Period 2. Study has no wash-out period.

Serious adverse events	All Participants: Training Period	RLZ Total	Self-Administration Period 1 and 2: RLZ MP
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 62 (1.61%)	7 / 62 (11.29%)	1 / 53 (1.89%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lung cancer metastatic			

subjects affected / exposed	0 / 62 (0.00%)	1 / 62 (1.61%)	0 / 53 (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
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 62 (0.00%)	1 / 62 (1.61%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Myasthenia gravis			
subjects affected / exposed	1 / 62 (1.61%)	2 / 62 (3.23%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 62 (0.00%)	1 / 62 (1.61%)	0 / 53 (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
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 62 (0.00%)	1 / 62 (1.61%)	0 / 53 (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
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	0 / 62 (0.00%)	1 / 62 (1.61%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Self-Administration Period 1 and 2: RLZ SRD		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 54 (5.56%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Lung cancer metastatic			
subjects affected / exposed	1 / 54 (1.85%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 54 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Myasthenia gravis			
subjects affected / exposed	0 / 54 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Transient ischaemic attack			
subjects affected / exposed	1 / 54 (1.85%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 54 (1.85%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	0 / 54 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	All Participants: Training Period	RLZ Total	Self-Administration Period 1 and 2: RLZ MP
Total subjects affected by non-serious adverse events			
subjects affected / exposed	19 / 62 (30.65%)	24 / 62 (38.71%)	6 / 53 (11.32%)

Nervous system disorders Headaches subjects affected / exposed occurrences (all)	12 / 62 (19.35%) 21	13 / 62 (20.97%) 29	1 / 53 (1.89%) 1
General disorders and administration site conditions Pyrexia subjects affected / exposed occurrences (all)	4 / 62 (6.45%) 4	6 / 62 (9.68%) 10	3 / 53 (5.66%) 5
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	4 / 62 (6.45%) 4	5 / 62 (8.06%) 5	1 / 53 (1.89%) 1
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all) COVID-19 subjects affected / exposed occurrences (all)	0 / 62 (0.00%) 0 4 / 62 (6.45%) 4	5 / 62 (8.06%) 6 7 / 62 (11.29%) 7	2 / 53 (3.77%) 2 1 / 53 (1.89%) 1

Non-serious adverse events	Self-Administration Period 1 and 2: RLZ SRD		
Total subjects affected by non-serious adverse events subjects affected / exposed	6 / 54 (11.11%)		
Nervous system disorders Headaches subjects affected / exposed occurrences (all)	4 / 54 (7.41%) 7		
General disorders and administration site conditions Pyrexia subjects affected / exposed occurrences (all)	1 / 54 (1.85%) 1		
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0		
Infections and infestations			

Nasopharyngitis subjects affected / exposed occurrences (all)	3 / 54 (5.56%) 3		
COVID-19 subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
04 November 2022	Protocol Amendment 2 (dated 04 Nov 2022) was implemented to provide an update on the safety information in line with the updated Investigator's Brochure (dated Sep 2022), updates on the adverse events of special monitoring (AESM), and an update on the planned fixed dose of rozanolixizumab based on study participants' body weight. The secondary endpoint related to the occurrence of medication errors, the Schedule of Activities, and the criteria for IMP discontinuation and participant discontinuation from the study were also updated. Additional updates to provide further clarity on the protocol were also incorporated. This amendment was considered to be substantial based on the criteria set forth in Article 10(a) of Directive 2001/20/EC of the European Parliament and the Council of the European Union.
07 September 2023	Protocol Amendment 4 (dated 07 Sep 2023) was implemented to align with the approved label in the USA and with the proposed dosing regimen under review in Europe. This amendment was considered to be substantial based on the criteria set forth in Article 10(a) of Directive 2001/20/EC of the European Parliament and the Council of the European Union.
30 November 2023	Protocol Amendment 5 (dated 30 Nov 2023) was implemented to update the text and reflect the total number of participants screened, and to update the End of Study definition. This amendment was considered to be substantial based on the criteria set forth in Article 10(a) of Directive 2001/20/EC of the European Parliament and the Council of the European Union.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported