

# Quality of life in patients with generalized myasthenia gravis receiving rozanolixizumab: *Post hoc* analysis of MycarinG

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## Introduction

- MG is a chronic autoimmune disease characterised by fluctuating muscle weakness fatigability that can significantly impact many aspects of patients' HRQoL<sup>1,2</sup>
- The MG-QoL15r is a PRO instrument designed to investigate the physiological, social and emotional impact of MG-specific impairment, comprising 15 items (total score: 0–30), where higher scores reflect worse HRQoL<sup>3</sup>
- In the MycarinG study (NCT03971422), rozanolixizumab significantly improved MG-specific outcomes versus placebo in patients with gMG<sup>4</sup>
- Here, we evaluate the impact of rozanolixizumab on different facets of HRQoL in patients with gMG, using three themes of the MG-QoL15r in a *post hoc* analysis of MycarinG data

## Methods

- Patients were randomised 1:1:1 to receive once-weekly SC rozanolixizumab 7 mg/kg, rozanolixizumab 10 mg/kg or placebo for 6 weeks (to Day 43), followed by an 8-week observation period
- LS mean (95% CI) CFB in MG-QoL15r at Day 43 was determined *post hoc* for the three treatment groups using an MMRM ANCOVA model
- The 15 items of the MG-QoL15r were grouped into three themes: physical (score range: 0–14), social (score range: 0–8) and emotional (score range: 0–8; **Table 1**)
  - Descriptive analyses of the CFB in MG-QoL15r scores at Day 43 for each theme were conducted

## Results

- Overall, 200 patients received rozanolixizumab 7 mg/kg (n=66), rozanolixizumab 10 mg/kg (n=67) or placebo (n=67)
- LS mean (SE) CFB in MG-QoL15r total score at Day 43 was greater in both rozanolixizumab groups than in the placebo group (**Figure 1**)
- Across the three themes, mean CFB in scores were greater in the rozanolixizumab groups than in the placebo group (**Figure 2**)
- At baseline, the majority of patients reported MG symptoms impacting their QoL across all three themes represented by scores  $\geq 1$  (rozanolixizumab 7 mg/kg: 90.9% [n=60]; rozanolixizumab 10 mg/kg: 90.9% [n=60]; placebo: 94.0% [n=63])
- At Day 43, the proportions of patients who reported no impact of symptoms on QoL across each of the three themes were greater for both rozanolixizumab dose groups compared with the placebo group (**Table 2**)
  - A complete absence of HRQoL impairment, indicated by scores of 0 across all three themes, was reported at Day 43 in 7.7% (n=5) and 10.6% (n=7) of patients in the rozanolixizumab 7 mg/kg and 10 mg/kg groups, respectively, compared with no patients in the placebo group
- Overall, rozanolixizumab was generally well tolerated and demonstrated an acceptable safety profile
  - TEAEs occurred in 81.3% (n=52/64), 82.6% (n=57/69) and 67.2% (n=45/67) of patients treated with rozanolixizumab 7 mg/kg, 10 mg/kg and placebo, respectively; most were mild or moderate
  - The most frequent TEAEs were headache (rozanolixizumab 7 mg/kg: 45.3%; 10 mg/kg: 37.7%; placebo: 19.4%), diarrhoea (7 mg/kg: 25.0%; 10 mg/kg: 15.9%; placebo: 13.4%) and pyrexia (7 mg/kg: 12.5%; 10 mg/kg: 20.3%; placebo: 1.5%)

## Summary and conclusions



Improvements in MG-QoL15r total score were greater and nominally statistically significant in the rozanolixizumab treatment groups compared with the placebo group



Mean CFB at Day 43 was greater in physical, social and emotional themes of the MG-QoL15r for both rozanolixizumab groups compared with placebo

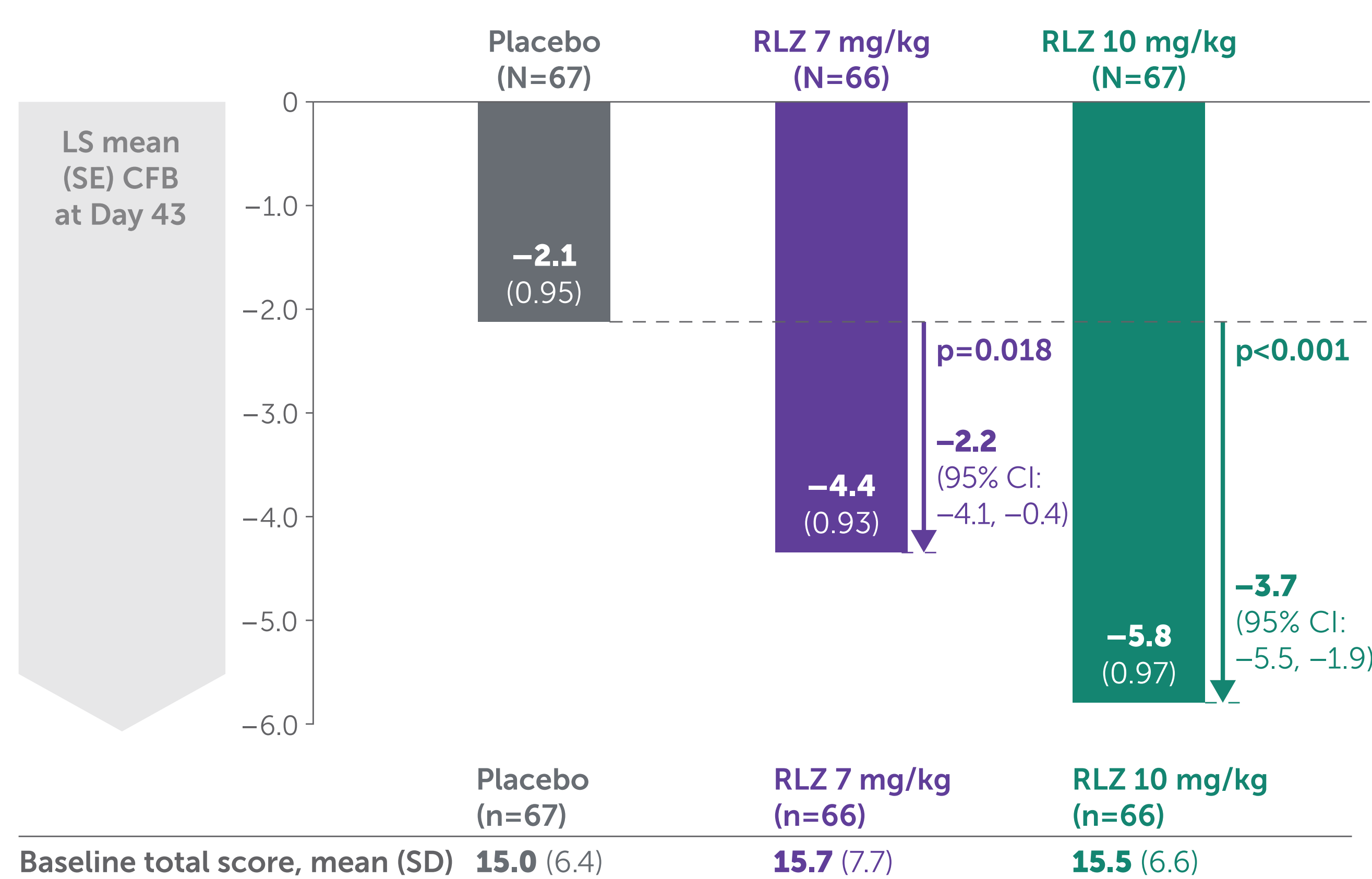


Across the three themes, greater proportions of patients in the rozanolixizumab groups achieved an absence of impact of symptoms on HRQoL as measured by the MG-QoL15r

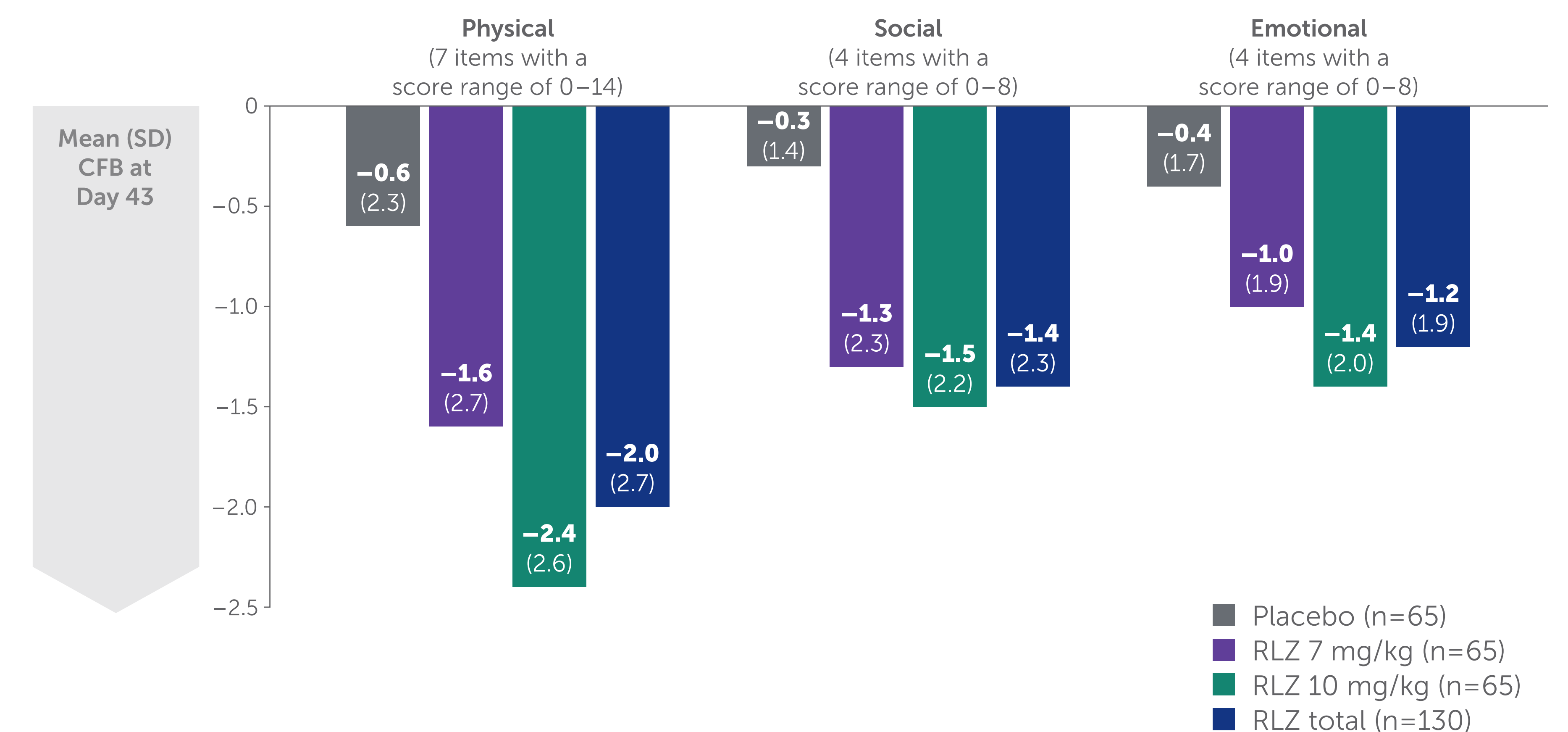


These data demonstrate that patients benefit from rozanolixizumab treatment across the breadth of impacts that MG symptoms have on patients' HRQoL

**Figure 1** LS mean CFB in MG-QoL15r total score at Day 43 was greater with both rozanolixizumab doses than with placebo



**Figure 2** Across the three themes of the MG-QoL15r, mean CFB at Day 43 was greater with both rozanolixizumab doses than with placebo



**Table 1** MG-QoL15r items were assigned to three themes

Please indicate how true each statement has been (over the past few weeks)	Physical	Social	Emotional
1. I am frustrated by my MG			X
2. I have trouble using my eyes because of my MG (e.g. double vision)	X		
3. I have trouble eating because of my MG	X		
4. I have limited my social activity because of my MG		X	
5. My MG limits my ability to enjoy hobbies and fun activities		X	
6. I have trouble meeting the needs of my family because of my MG		X	
7. I have to make plans around my MG		X	
8. I am bothered by limitations in my performing at work (include work at home) because of my MG			X
9. I have difficulty speaking due to MG	X		
10. I have lost some personal independence because of my MG (e.g. driving, shopping, running errands)	X		
11. I am depressed about my MG			X
12. I have trouble walking due to MG	X		
13. I have trouble getting around in public places because of my MG	X		
14. I feel overwhelmed by my MG			X
15. I have trouble performing my personal grooming needs due to MG	X		

**Table 2** Across the three themes, there was a greater increase in the proportion of patients with no impact of symptoms on QoL (score of 0) at Day 43 in both rozanolixizumab dose groups than with placebo

Theme	Patients with score of 0 at baseline, n (%)			Patients with score of 0 at Day 43, n (%)		
	Placebo	RLZ 7 mg/kg	RLZ 10 mg/kg	Placebo	RLZ 7 mg/kg	RLZ 10 mg/kg
Physical	0 (0)	4 (6.1)	2 (3.0)	2 (3.1)	11 (16.9)	12 (18.2)
Social	3 (4.5)	3 (4.5)	3 (4.5)	3 (4.6)	11 (16.9)	14 (21.2)
Emotional	1 (1.5)	2 (3.0)	4 (6.1)	2 (3.1)	12 (18.5)	15 (22.7)
Physical and social	0 (0)	2 (3.0)	1 (1.5)	0 (0)	8 (12.1)	9 (13.4)
Physical and emotional	0 (0)	1 (1.5)	0 (0)	0 (0)	6 (9.1)	9 (13.4)
Social and emotional	0 (0)	1 (1.5)	2 (3.0)	0 (0)	7 (10.6)	10 (14.9)
Physical, social and emotional	0 (0)	1 (1.5)	0 (0)	0 (0)	5 (7.7)	7 (10.6)

**Abbreviations:** ANCOVA, analysis of covariance; CFB, change from baseline; CI, confidence interval; gMG, generalised myasthenia gravis; HRQoL, health-related quality of life; LS, least squares; MG, myasthenia gravis; MG-QoL15r, Myasthenia Gravis Quality of Life 15-item Scale – Revised; MMRM, mixed model for repeated measures; PRO, patient-reported outcome; SC, subcutaneous; SD, standard deviation; SE, standard error.

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