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Measuring the effect of rozanolixizumab treatment in the MycarinG study using the Myasthenia Gravis Impairment Index

Carolina Barnett-Tapia[1,2], Elena Cortés Vicente[3], Robert M. Pascuzzi[4], Kimiaki Utsugisawa[5], Jos Bloemers[6], Fiona Grimson[7], Thaïs Tarancón[8] and Vera Bril[1] on behalf of the MycarinG study team

[1]Ellen and Martin Prosserman Centre for Neuromuscular Diseases, Toronto General Hospital, University of Toronto, Toronto, Ontario, Canada; [2]Institute of Health Policy, Management and Evaluation, University of Toronto, Toronto, Ontario, Canada; [3]Neuromuscular Diseases Unit, Hospital de la Santa Creu i Sant Pau, Barcelona, Spain; [4]Neurology Department, Indiana University School of Medicine, Indiana University Health, Indianapolis, IN, USA; [5]Department of Neurology, Hanamaki General Hospital, Hanamaki, Japan; [6]UCB, Brussels, Belgium; [7]UCB, Slough, UK; [8]UCB, Madrid, Spain

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Introduction

- gMG is a chronic disease characterized by fluctuating muscle weakness fatigability that can significantly impact patients' quality of life[1]
- In the randomized, double-blind, placebo-controlled MycarinG study (NCT03971422), one 6-week cycle of rozanolixizumab significantly improved MG-ADL and QMG total scores versus placebo and was generally well tolerated in patients with gMG[2] (**Figure 1**)
- The MGII incorporates patients' perspectives (22-item questionnaire) and physician evaluation (6 items) of the impairments caused by MG symptoms[3]
- This exploratory analysis evaluated the impact of rozanolixizumab on MG symptoms using the MGII in MycarinG

Methods

- Patients were aged ≥18 years with AChR Ab+ or MuSK Ab+ gMG, MGFA Disease Class II–IVa, MG-ADL score ≥3 (for non-ocular symptoms) and QMG score ≥11
- Patients were randomized 1:1:1 to once-weekly subcutaneous rozanolixizumab 7 mg/kg, rozanolixizumab 10 mg/kg or placebo for 6 weeks
- The primary endpoint was CFB to Day 43 in MG-ADL score; secondary endpoints included CFB to Day 43 in QMG score
- Exploratory endpoints included CFB to Day 43 in MGII total score (range: 0–84) and ocular and generalized subscores (range: 0–23 and 0–61, respectively); MGII was an optional assessment
- *Post hoc* analyses included MGII responder rates (defined as a ≥5.5-point improvement in the MGII total score[4]) and item-level analyses

Results

- Overall, 200 patients received rozanolixizumab 7 mg/kg (n=66), rozanolixizumab 10 mg/kg (n=67) or placebo (n=67)
- 144/200 (72.0%) patients completed the MGII at baseline and at Day 43
- Rozanolixizumab treatment resulted in a greater mean CFB to Day 43 in MGII total score compared with placebo (**Figure 2**)
  - Mean CFB in ocular and generalized subscores was consistent with the total score (**Figure 2**)
- At Day 43, 70.1% of rozanolixizumab-treated patients were MGII responders compared with 40.4% of placebo-treated patients (**Figure 3**)
- Across most individual items, greater proportions of the rozanolixizumab groups achieved a score of 0 (i.e., symptom absence) at Day 43 compared with the placebo group, in patients with an item score of ≥1 at baseline (**Table 1**)
- Overall, 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, rozanolixizumab 10 mg/kg and placebo, respectively; most events were mild or moderate

Summary and conclusions

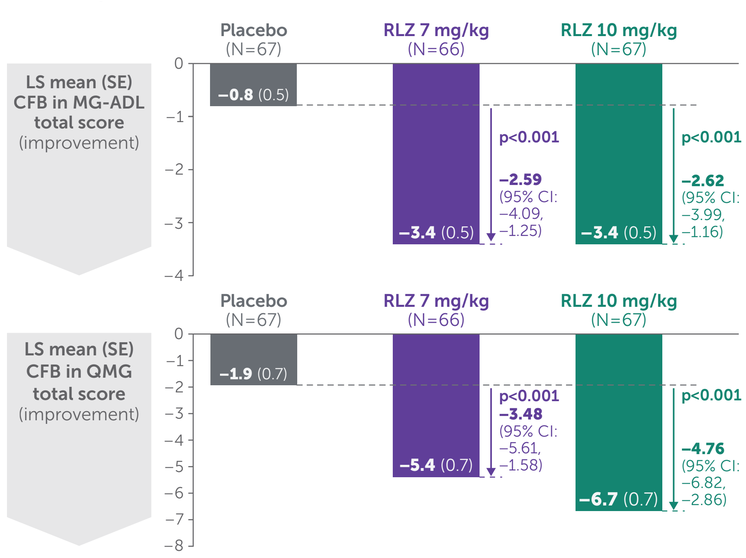
In MycarinG, statistically significant and clinically meaningful improvements from baseline were observed across several MG-specific outcomes with rozanolixizumab treatment compared with placebo

Improvements measured by the MGII were consistently greater in rozanolixizumab-treated patients than in placebo-treated patients across the MGII total score, ocular and generalized subscores, and in an item-level analysis

These analyses of MGII data from MycarinG further support the primary and secondary efficacy findings to highlight the treatment benefit of rozanolixizumab

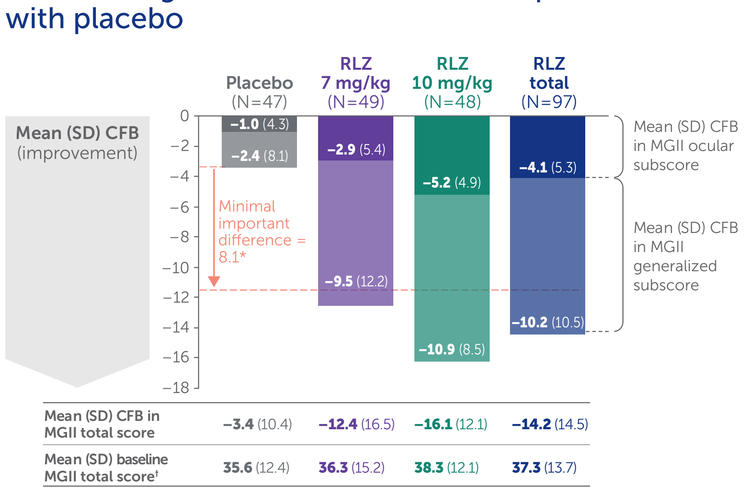
These data also demonstrate the utility of the MGII in evaluating both ocular and generalized symptoms following treatment for gMG

Figure 1 One 6-week cycle of rozanolixizumab significantly improved MG-ADL and QMG total scores versus placebo



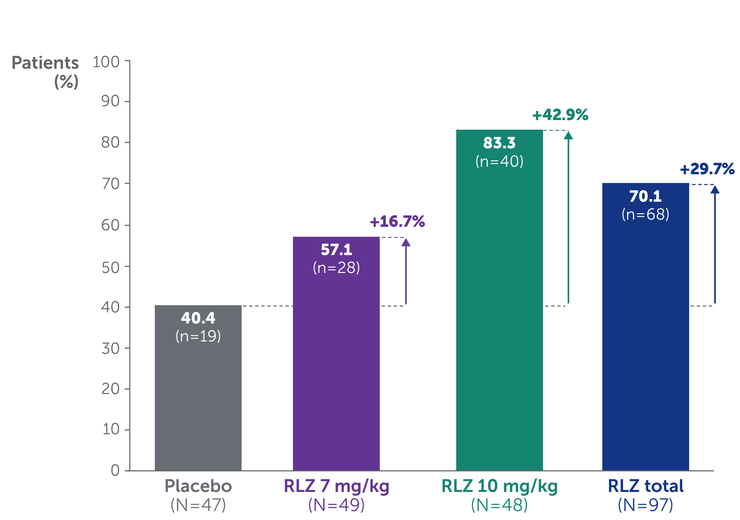
Randomized set.

Figure 2 At Day 43, rozanolixizumab treatment showed improvements in mean CFB in MGII total, ocular and generalized subscores compared with placebo



Randomized set. *Minimal important difference in MGII total score is 8.1 points for groups;[4] therefore, the threshold for between-group minimal important difference is −11.5 points when determined from the placebo mean CFB of −3.4. †Patients with MGII data at baseline: N=53, N=55, N=54 and N=109 in the placebo, RLZ 7 mg/kg, RLZ 10 mg/kg and RLZ total groups, respectively.

Figure 3 At Day 43, greater proportions of patients receiving rozanolixizumab were MGII responders compared with placebo



Randomized set. Responders were defined as patients who achieved the minimal important difference in MGII total score of 5.5 points for individuals.[4] n represents the number of patients who were MGII responders at Day 43; N represents the number of patients who completed the MGII assessment at Day 43.

Table 1 Greater proportions of rozanolixizumab groups achieved an MGII individual item score of 0 (i.e., symptom absence) at Day 43 compared with placebo

(a) Problems with your eyes

0–<10% | 10–<20% | 20–<30% | 30–<40% | 40–<50% | 50–100%

Item	Patients achieving MGII score of 0 at Day 43: Placebo % (n/N)	RLZ 7 mg/kg % (n/N)	RLZ 10 mg/kg % (n/N)	RLZ total % (n/N)
Double vision throughout the day	**17.6** (6/34)	**14.3** (4/28)	**33.3** (11/33)	**24.6** (15/61)
Double vision with activities	**19.4** (6/31)	**17.9** (5/28)	**32.3** (10/31)	**25.4** (15/59)
Severity of double vision	**17.1** (6/35)	**13.8** (4/29)	**40.0** (14/35)	**28.1** (18/64)
Diplopia*	**6.1** (2/33)	**16.7** (5/30)	**48.6** (17/35)	**33.8** (22/65)
Eyelid drooping throughout the day	**11.1** (4/36)	**22.9** (8/35)	**54.1** (20/37)	**38.9** (28/72)
Eyelid drooping with activities	**8.8** (3/34)	**18.8** (6/32)	**63.9** (23/36)	**42.6** (29/68)
Severity of eyelid drooping	**8.3** (3/36)	**22.2** (8/36)	**54.1** (20/37)	**38.4** (28/73)
Ptosis*	**13.2** (5/38)	**29.4** (10/34)	**43.8** (14/32)	**36.4** (24/66)

Randomized set. Baseline is the last available value prior to the first injection of study drug in the treatment period or, if missing, the screening value. *Examination item.

(b) Problems eating

0–<10% | 10–<20% | 20–<30% | 30–<40% | 40–<50% | 50–100%

Item	Patients achieving MGII score of 0 at Day 43: Placebo % (n/N)	RLZ 7 mg/kg % (n/N)	RLZ 10 mg/kg % (n/N)	RLZ total % (n/N)
Difficulty swallowing	**13.9** (5/36)	**34.5** (10/29)	**41.9** (13/31)	**38.3** (23/60)
Chewing different types of food	**15.6** (5/32)	**45.2** (14/31)	**35.7** (10/28)	**40.7** (24/59)
Chewing tiredness/fatigue	**12.9** (4/31)	**41.9** (13/31)	**45.2** (14/31)	**43.5** (27/62)
Lower facial strength*	**15.4** (4/26)	**40.7** (11/27)	**50.0** (13/26)	**45.3** (24/53)

Randomized set. Baseline is the last available value prior to the first injection of study drug in the treatment period or, if missing, the screening value. *Examination item.

(c) Problems speaking and breathing

0–<10% | 10–<20% | 20–<30% | 30–<40% | 40–<50% | 50–100%

Item	Patients achieving MGII score of 0 at Day 43: Placebo % (n/N)	RLZ 7 mg/kg % (n/N)	RLZ 10 mg/kg % (n/N)	RLZ total % (n/N)
Voice changes through the day	**21.9** (7/32)	**35.5** (11/31)	**44.8** (13/29)	**40.0** (24/60)
Voice changes with prolonged conversation	**11.1** (4/36)	**35.3** (12/34)	**33.3** (11/33)	**34.3** (23/67)
Severity of voice changes	**10.8** (4/37)	**34.3** (12/35)	**30.3** (10/33)	**32.4** (22/68)
Speech clarity through the day	**35.7** (10/28)	**48.1** (13/27)	**61.5** (16/26)	**54.7** (29/53)
Speech clarity with prolonged conversation	**25.0** (8/32)	**42.9** (12/28)	**51.9** (14/27)	**47.3** (26/55)
Severity of speech changes	**24.2** (8/33)	**33.3** (10/30)	**51.7** (15/29)	**42.4** (25/59)
Difficulty breathing	**5.6** (2/36)	**17.1** (6/35)	**36.4** (12/33)	**26.5** (18/68)

Randomized set. Baseline is the last available value prior to the first injection of study drug in the treatment period or, if missing, the screening value.

(d) Generalized symptoms

0–<10% | 10–<20% | 20–<30% | 30–<40% | 40–<50% | 50–100%

Item	Patients achieving MGII score of 0 at Day 43: Placebo % (n/N)	RLZ 7 mg/kg % (n/N)	RLZ 10 mg/kg % (n/N)	RLZ total % (n/N)
Overall physical tiredness	**8.7** (4/46)	**20.5** (9/44)	**22.0** (9/41)	**21.2** (18/85)
Arm weakness severity	**8.9** (4/45)	**24.4** (10/41)	**17.5** (7/40)	**21.0** (17/81)
Arm weakness with prolonged use	**7.0** (3/43)	**22.5** (9/40)	**19.5** (8/41)	**21.0** (17/81)
Arm endurance*	**6.7** (3/45)	**23.3** (10/43)	**29.3** (12/41)	**26.2** (22/84)
Leg weakness severity	**2.2** (1/45)	**13.2** (5/38)	**18.4** (7/38)	**15.8** (12/76)
Leg weakness with prolonged use	**2.3** (1/44)	**14.3** (5/35)	**19.5** (8/41)	**17.1** (13/76)
Leg endurance*	**4.2** (2/48)	**10.9** (5/46)	**22.7** (10/44)	**16.7** (15/90)
Neck weakness	**26.3** (10/38)	**12.9** (4/31)	**44.4** (16/36)	**29.9** (20/67)
Neck endurance*	**13.0** (6/46)	**24.3** (9/37)	**41.0** (16/39)	**32.9** (25/76)

Randomized set. Baseline is the last available value prior to the first injection of study drug in the treatment period or, if missing, the screening value. *Examination item.

Abbreviations: Ab+, antibody positive; AChR, acetylcholine receptor; CFB, change from baseline; CI, confidence interval; gMG, generalized myasthenia gravis; LS, least squares; MG, myasthenia gravis; MG-ADL, Myasthenia Gravis Activities of Daily Living; MGFA, Myasthenia Gravis Foundation of America; MGII, Myasthenia Gravis Impairment Index; MuSK, muscle-specific tyrosine kinase; QMG, Quantitative Myasthenia Gravis; RLZ, rozanolixizumab; SD, standard deviation; SE, standard error; TEAE, treatment-emergent adverse event.

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