Patient preferences and experience with self-administration of rozanolixizumab in generalised myasthenia gravis: The MG0020 study

Marta Cheli[1], Carlo Antozzi[2], Tomasz Berkowicz[3], Artur Drużdż[4], Rachana K. Gandhi Mehta[5], M. Isabel Leite[6], Zabeen K. Mahuwala[7], Jana Zschüntzsch[8], Marion Boehnlein[9], Andreea Lavrov[9], Mark Morris[10], Puneet Singh[10] and Vera Bril[11] on behalf of the MG0020 study team

[1]Neuroimmunology and Muscle Pathology Unit, Multiple Sclerosis Center, Fondazione Istituto di Ricovero e Cura a Carattere Scientifico, Istituto Nazionale Neurologico Carlo Besta, Milan, Italy; [2]Immunotherapy and Apheresis Unit and Neuroimmunology and Muscle Pathology Unit, Fondazione Istituto di Ricovero e Cura a Carattere Scientifico, Istituto Neurologico Carlo Besta [3]Miejskie Centrum Medyczne JONSCHER im. dr. Karola Jonschera w Łodzi, Łódź, Poland; [4]Department of Neurology, Municipal Hospital, Poznań, Poland; [5]Department of Neurology, Wake Forest University School of Medicine, Winston-Salem, NC, USA; [6]Nuffield Department of Clinical Neurosciences, University of Oxford, Oxford, UK; [7]Department of Neuromuscular Medicine, Epilepsy and Clinical Neurophysiology, University of Kentucky, Lexington, KY, USA; [8]Department of Neurology, University Medical Center Göttingen, Göttingen, Germany; [9]UCB, Monheim, Germany; [10]UCB, Slough, UK; [11]Ellen and Martin Prosserman Centre for Neuromuscular Diseases, Toronto General Hospital, University of Toronto, Toronto, Ontario, Canada

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Introduction

- gMG is a chronic autoimmune disease that can require long-term treatment[1]
- Rozanolixizumab is a humanised IgG4 mAb FcRn blocker. Following the MycarinG study (NCT03971422),[2] rozanolixizumab was approved for SC administration by HCPs using a programmable infusion pump for the treatment of adults with anti-AChR Ab+ or anti-MuSK Ab+ gMG[3]
- To provide an option for patients to self-administer rozanolixizumab, the manual push and infusion pump methods were evaluated[4]
- Here, we report on the success of rozanolixizumab self-administration in the MG0020 study (NCT05681715), and on patient preferences and experience of self-administration

Methods

- MG0020 was a Phase 3, open-label, randomised, two-period, two-sequence crossover study (**Figure 1**)
- Patients were aged ≥18 years, with gMG, serum total IgG level of ≥5.5–16.0 g/L, body weight ≥35 kg, and either rozanolixizumab-naïve or non-naïve at screening
- The primary endpoint was successful self-administration of rozanolixizumab, evaluated by an HCP at Weeks 12 and 18, and defined as choosing the correct infusion site, administering subcutaneously and delivering the intended dose; secondary endpoints included the occurrence of TEAEs
- Additional endpoints included patient preferences, patient satisfaction (pre-treatment and post-treatment SIAQ scores), and CFB in total IgG and MG-ADL score

Results

- Overall, 62 patients entered MG0020 (safety set) and 55 were randomised (randomised safety set) to Sequence 1 (n=28) or Sequence 2 (n=27)
- Baseline characteristics were generally well balanced between the sequences (**Table 1**)
- All patients in both sequences successfully self-administered 100% of their infusions (**Figure 2**), both in clinic and at home
- Overall, 75.8% (n=47/62) of patients experienced a TEAE; the majority were mild or moderate and occurred during the first 6 weeks
  - The safety profile was consistent with the known profile of HCP-administered rozanolixizumab
- The duration of infusion was generally shorter with manual push than with infusion pump, leading to a higher infusion rate for manual push
  - No safety trends or local tolerability issues were associated with the higher infusion rate for manual push
- Self-administration of rozanolixizumab via manual push was the preferred method (**Figure 3**)
- Mean post-treatment SIAQ scores were high, indicating a positive self-administration experience (**Figure 4**)
- There was a rapid and sustained reduction in median total IgG within 1 week through to the end of the second Self-Administration Period (**Figure 5**)
- Clinically significant improvements in MG-ADL score (≥2-point decrease from baseline) were observed in both sequences at Week 7; improvements were consistent across the two Self-Administration Periods

Summary and conclusions

MG0020 was a Phase 3, open-label, randomised, crossover study evaluating self-administration of rozanolixizumab in patients with gMG

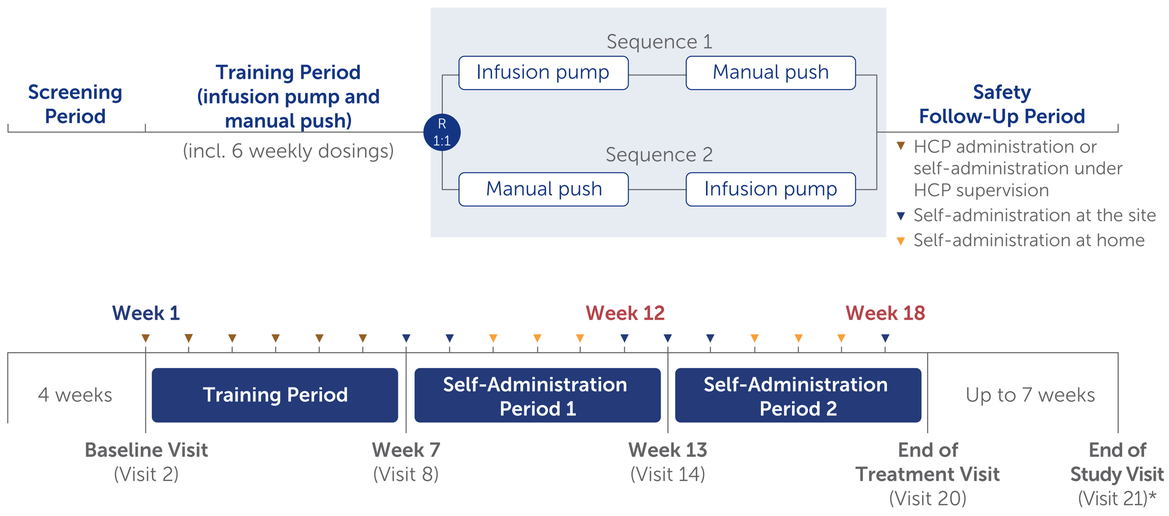
All patients successfully self-administered rozanolixizumab using both manual push and infusion pump methods, in clinic and at home

Self-administration via manual push was the preferred method, and a positive experience was reported with rozanolixizumab self-administration

These findings support manual push or infusion pump self-administration of rozanolixizumab in patients with gMG

Based on data from MG0020, self-administration of rozanolixizumab via manual push and infusion pump methods following training by an HCP has been approved in the EU[3] and Japan[5]

Figure 1 MG0020 was a Phase 3, open-label, randomised, two-period, two-sequence crossover study



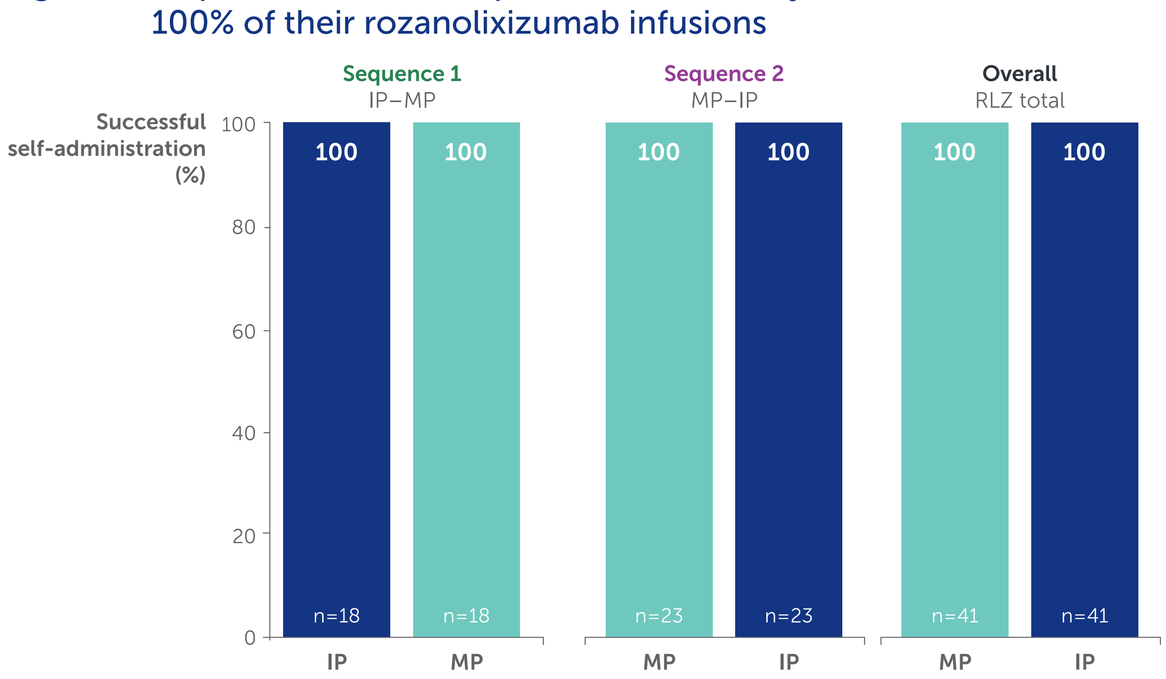
Patients were randomised 1:1 at Week 7 to self-administer rozanolixizumab, following the investigators' confirmation of eligibility to perform self-administration. *Patients completing all treatment periods, including the End of Treatment Visit, and moving on to either a post-study access programme or commercially available rozanolixizumab during the Safety Follow-Up Period underwent an earlier End of Study Visit prior to this move.

Table 1 Baseline characteristics were generally well balanced between sequences

		Self-administration population (RSS)			Overall population (SS)
		IP–MP (N=28)	MP–IP (N=27)	RLZ total (N=55)	RLZ total (N=62)
Age, years, mean (SD)		**52.9** (16.3)	**53.4** (15.7)	**53.1** (15.9)	**53.3** (15.7)
Sex, female, n (%)		**16** (57.1)	**15** (55.6)	**31** (56.4)	**35** (56.5)
MG-ADL score, mean (SD)		**7.1** (3.9)	**7.5** (3.9)	**7.3** (3.9)	**7.3** (3.9)
MGFA Disease Class, n (%)	I	**1** (3.6)	**0**	**1** (1.8)	**1** (1.6)
	II	**12** (42.9)	**12** (44.4)	**24** (43.6)	**28** (45.2)
	III	**15** (53.6)	**15** (55.6)	**30** (54.5)	**33** (53.2)
	IV–V	**0**	**0**	**0**	**0**
RLZ-naïve at study entry, n (%)*		**19** (67.9)	**18** (66.7)	**37** (67.3)	**42** (67.7)
Age at initial MG diagnosis, years, mean (SD)		**46.8** (18.9)	**44.6** (18.4)	**45.7** (18.5)	**45.8** (18.3)
Duration of disease, years, mean (SD)†		**6.4** (8.1)	**9.4** (9.4)	**7.9** (8.8)	**7.9** (8.5)
Myasthenic crisis in the past, n (%)		**8** (28.6)	**6** (22.2)	**14** (25.5)	**15** (24.2)
Anti-AChR Ab+, n (%)		**21** (75.0)	**20** (74.1)	**41** (74.5)	**46** (74.2)
Anti-MuSK Ab+, n (%)		**3** (10.7)	**2** (7.4)	**5** (9.1)	**5** (8.1)
Anti-LRP-4 Ab+, n (%)		**0**	**0**	**0**	**1** (1.6)
Prior gMG medications, n (%)‡	Parasympathomimetics	–	–	–	**54** (87.1)
	Corticosteroids	–	–	–	**37** (59.7)
	Immunosuppressants	–	–	–	**31** (50.0)

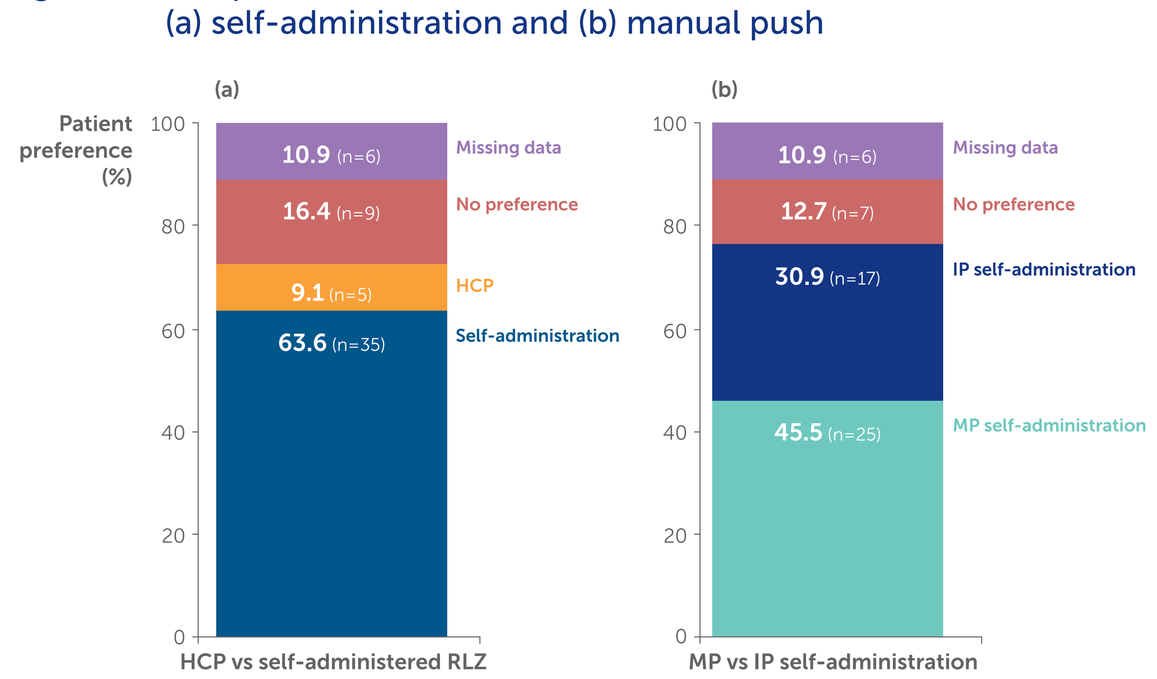
Safety set and randomised safety set. The safety set consisted of all patients who received at least one dose of RLZ (partial or full). The randomised safety set consisted of all patients who were included in the safety set and were randomised. *All non-naïve patients participated in the MG0007 study. †From diagnosis. ‡Prior medications include any medications that started before the first administration of RLZ. Data for prior gMG medications were captured prior to the Training Period and were therefore analysed in the safety set.

Figure 2 All patients in both sequences successfully self-administered 100% of their rozanolixizumab infusions



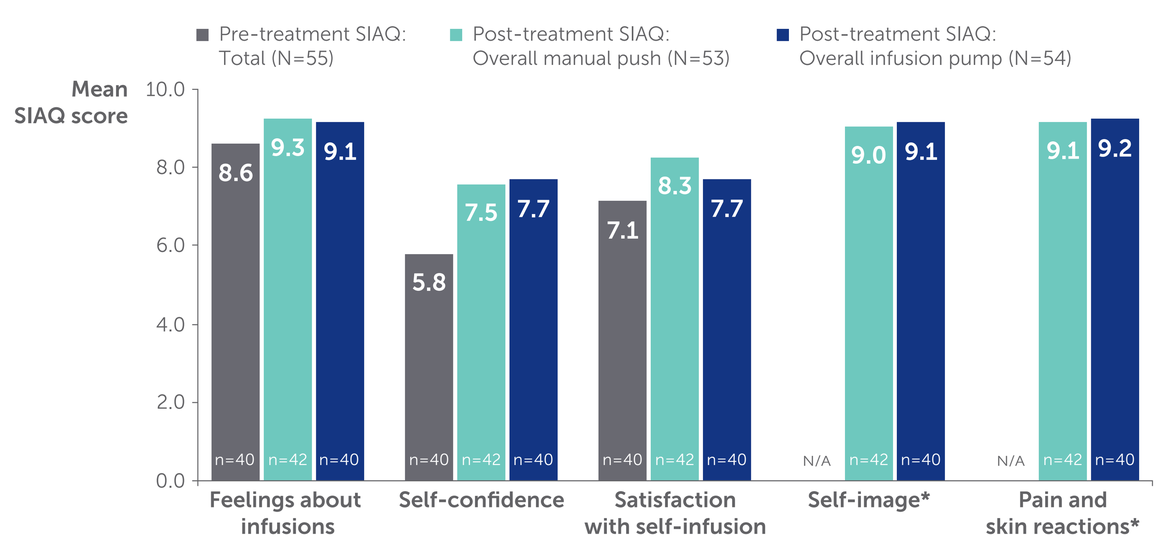
Primary efficacy analyses were performed on the full analysis set, which consisted of all patients who were in the safety set, were randomised and completed both Self-Administration Periods. Percentages are based on the number of patients with non-missing data.

Figure 3 The preferred method of rozanolixizumab administration was (a) self-administration and (b) manual push



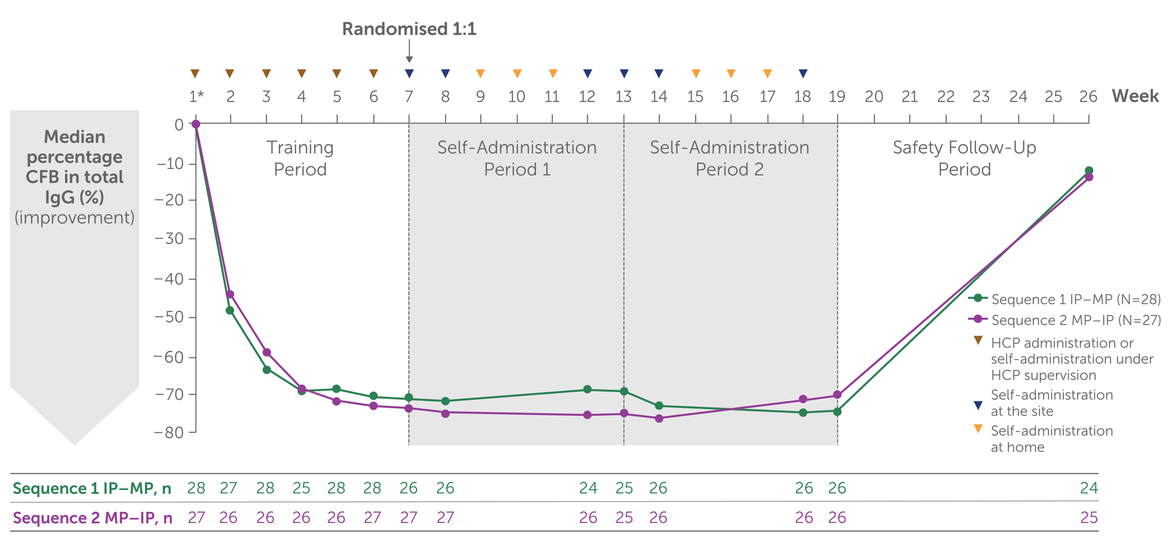
N=55. Randomised safety set. Questionnaire was administered at the last self-administration visit. Percentages are based on the number of patients with an assessment at Week 18. Self-administration includes study drug administration by patient or caregiver.

Figure 4 Pre- and post-treatment mean SIAQ scores by domain indicated a positive experience



Randomised safety set. Domain scores were calculated if ≥50% of items in the domain were completed; domain scores range from 0 to 10, with a higher score indicating a better experience. Pre-treatment SIAQ was completed by patients pre-dose at Week 1 and post-treatment SIAQ was completed after self-infusion at Weeks 11 and 17. The SIAQ (Infusion Version) is not available in Georgia (n=6) and Serbia (n=2). *Self-image and pain and skin reaction domains were not included in pre-treatment SIAQ data.

Figure 5 There was a rapid and sustained reduction in total IgG serum concentration



Randomised safety set. IgG values up to and including 8 weeks after the start date of rescue therapy were excluded. Mean (SD) baseline value was 9.85 (2.29) g/L for Sequence 1 (N=28) and 9.76 (2.78) g/L for Sequence 2 (N=27). *Baseline values were defined as the last available measurement before the first administration of the study drug at Week 1.

Abbreviations: Ab+, antibody positive; AChR, acetylcholine receptor; CFB, change from baseline; FcRn, neonatal fragment crystallisable receptor; gMG, generalised myasthenia gravis; HCP, healthcare professional; IgG, immunoglobulin G; IgG4, immunoglobulin G4; IP, infusion pump; LRP-4, low-density lipoprotein receptor-related protein 4; mAb, monoclonal antibody; MG-ADL, Myasthenia Gravis Activities of Daily Living; MGFA, Myasthenia Gravis Foundation of America; MP, manual push; MuSK, muscle-specific tyrosine kinase; R, randomised; RLZ, rozanolixizumab; SC, subcutaneous; SD, standard deviation; SIAQ, Self-Injection Assessment Questionnaire; TEAE, treatment-emergent adverse event.

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