A real-world, observational study of erenumab for migraine prevention in Canadian patients with prior ineffective prophylactic treatments

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Disclosures

The sponsor was involved in the design, interpretation and reporting of study results. DR, AF and NB are full time employees of Novartis Pharmaceuticals Canada Inc. **WJB has served on medical advisory boards or received speaker honoraria from** Allergan**, Novartis Pharmaceuticals Inc.**, Weber and Weber, Teva, Eli Lilly, and Lundbeck. **SS has received speaker honoraria from** Abbvie, Miravo, **Novartis Pharmaceuticals Inc.**, Teva, Eli Lilly, and Lundbeck. **RG has served on medical advisory boards or received speaker honoraria from** Allergan, **Novartis Pharmaceuticals Inc.**, Teva, Eli Lilly, and Lundbeck. **CL served on an advisory board for Novartis Pharmaceuticals Inc.,** received research support from Amgen Inc., Aralez, Eli Lilly and honoraria from Abbvie/Allergan. **EL, JG, and SC have received consultation fees from Novartis Pharmaceuticals Inc.**
GSP, JKM and JM were full time employees of IQVIA Solutions Canada Inc. (IQVIA) at the time of the study. Novartis Pharmaceuticals Canada Inc. contracted with IQVIA to manage the study.

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Background

- Migraine is a chronic neurological disorder affecting 1.04 billion individuals worldwide.[1] Patients with chronic and episodic migraine (CM and EM) are treated prophylactically using different drug classes with variable efficacy and substantial tolerability issues that often lead to treatment discontinuation.[2]
- Erenumab is a fully human monoclonal antibody targeting the calcitonin gene-related peptide (CGRP) receptor which previously demonstrated efficacy for migraine prevention in randomized controlled trials among patients who previously experienced inadequate effectiveness with up to four categories of prophylactic migraine therapies.[3]
- However, real-world evidence of erenumab effectiveness, safety, and usage in Canadian patients with difficult-to-treat CM and EM remains largely unreported.

Objectives

The “Migraine prevention with AimoviG: Informative Canadian real-world study” (MAGIC) was designed to assess the real-world effectiveness, safety, and usage of erenumab in Canadian migraine patients who previously experienced inadequate effectiveness or tolerability with two to six categories of prophylactic migraine therapies.

The **primary outcome** was the proportion of study participants experiencing ≥50% reduction in monthly migraine days (MMDs) at Week 12 from baseline.

Key **secondary outcomes** at Week 12 and Week 24 from baseline included the :

- proportion of participants achieving ≥50% reduction in MMDs CM and EM status
- proportion of participants achieving ≥50% reduction by the number of prior ineffective or intolerable prophylactic therapies
- change in the Patient Global Impression of Change (P-GIC) scale and Migraine Disability Assessment (MIDAS) questionnaire
- change in the CGI-Improvement (CGI-I) scales

Erenumab safety profile was assessed throughout the study from erenumab start.

Methods

Study Design

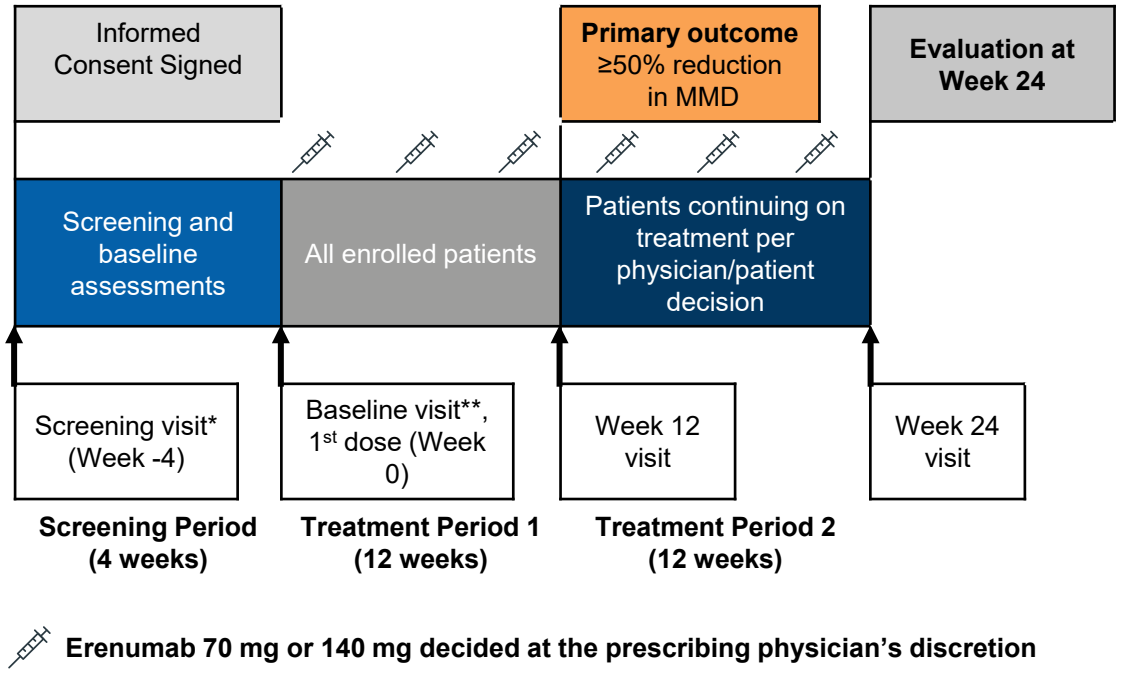
- MAGIC was a real-world, observational, prospective, open-label study conducted in adult patients with CM and EM who previously experienced inadequate effectiveness or tolerability with two to six categories of prophylactic migraine therapies.
- From April 2019 to April 2020, eligible patients with CM and EM were enrolled in a 2:1 ratio at 15 sites across Canada. As per routine clinical practice, patients received monthly subcutaneous injections of 70 mg or 140 mg erenumab as determined by the prescribing physician, independent of study participation.

Methods (Cont'd)

Study Design (Cont'd)

- Participants were enrolled at the Screening visit* (Week -4) and were asked to complete daily migraine assessments on an electronic diary (eDiary) application during the 28-day Screening Period. Eligible patients initiated erenumab therapy at the Baseline visit** (Week 0) to begin the Treatment Period 1 (TP1). At the end of TP1 (Week 12), eligible participants entered the TP2 to continue erenumab treatment for three additional months until Week 24 (**Figure 1**).

Figure 1. Study design



* To be enrolled at the Screening visit, patients must have had previously experienced inadequate efficacy or tolerability with two to six categories of prophylactic migraine therapies within five years prior to enrollment.

** To remain eligible for the study and initiate erenumab at the Baseline visit, participants were required to have ≥6 MMDs and demonstrate ≥80% eDiary compliance at the end of the Screening Period. If these criteria were not met, patients remained eligible for erenumab therapy as part of routine clinical practice, outside of study participation.

Methods (Cont'd)

Assessment Methods

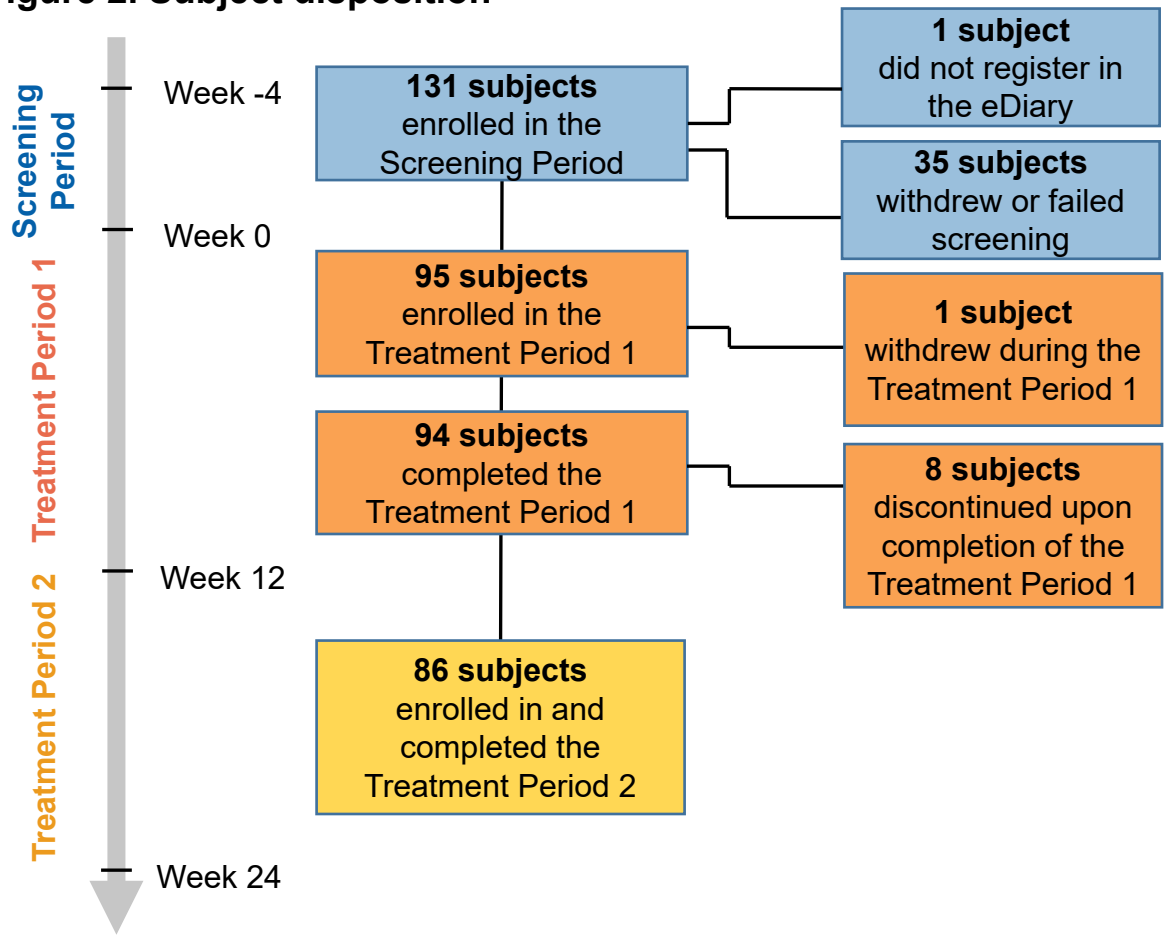
- Participant characteristics and medical history were obtained from medical charts.
- Participant self-reported daily assessments of migraine attacks using the eDiary.
- At baseline, Weeks 12 and 24, participants were invited to complete the MIDAS questionnaire.
- Change in participants' condition was assessed by participants and physicians using the P-GIC and CGI-I scales at Weeks 12 and 24.

Results

Disposition of Study Participants

- Among 131 recruited subjects, 95 initiated erenumab therapy, 86 of whom completed 24 weeks of treatment (**Figure 2**).

Figure 2. Subject disposition



Results (Cont'd)

Baseline Characteristics

- Participants were on average 41.4 years old at enrollment, 80.0% were female, and as planned, the majority were diagnosed with CM (67.4%).
- Most participants had previously experienced inadequate efficacy or tolerability with two (54.7%) or three (32.6%) categories of prophylactic migraine therapies and one participant (1.1%) had a similar experience with six categories (**Table 1**).

Table 1. Baseline characteristics

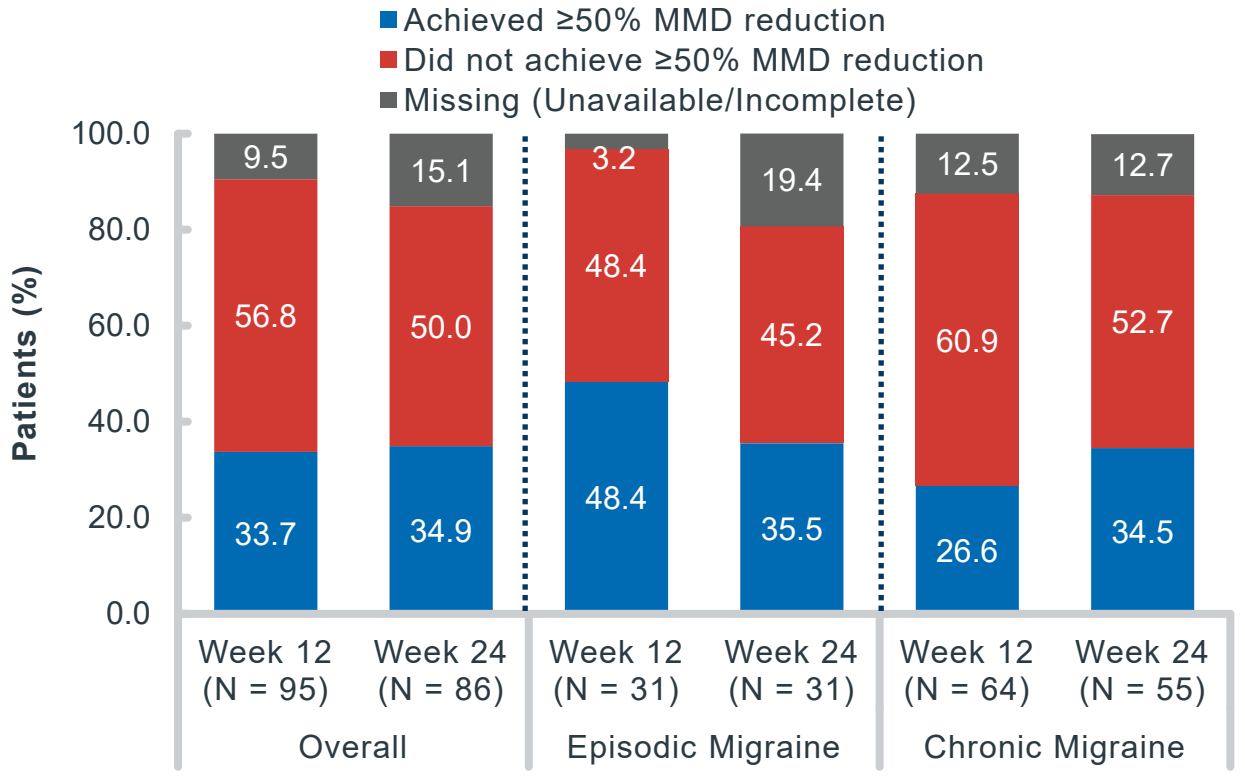
Baseline Characteristics	Participants (N=95)
Sex, Female n (%)	76 (80.0)
Weight (kg), mean (SD)	78.1 (19.5)
Height (cm), mean (SD)	167.3 (8.7)
BMI (kg/m^2), mean (SD)	28.0 (6.7)
Age (years), mean (SD)	
At enrollment	41.4 (11.3)
At migraine onset	19.4 (10.7)
At migraine diagnosis	27.1 (10.9)
Migraine type, n (%)	
Chronic Migraine	64 (67.4)
Episodic Migraine	31 (32.6)
Monthly Migraine Days (MMD), mean (SD)	15.7 (6.1)
Number of categories of prophylactic migraine therapies with inadequate efficacy or tolerability 5 years prior to screening period, n (%)	
2	52 (54.7)
3	31 (32.6)
4	11 (11.6)
5	0 (0.0)
6	1 (1.1)
Medication overuse during screening period, n (%)	68 (71.6)

Results (Cont'd)

MMDs

- At Week 12, 32/95 (33.7%) participants experienced ≥50% reduction in MMD. At Week 24, 30/86 (34.9%) participants achieved ≥50% reduction in MMD (**Figure 3**).
- Among EM subjects, ≥50% reduction in MMD was observed in 15/31 (48.4%) at Week 12, and 11/31 (35.5%) at Week 24 (**Figure 3**).
- Among CM subjects, ≥50% reduction in MMD was 17/64 (26.6%) at week 12 and 19/55 (34.5%) at week 24 (**Figure 3**).

Figure 3. Proportion of patients who achieved ≥50% MMD reduction at 12 and 24 weeks of erenumab therapy by migraine type

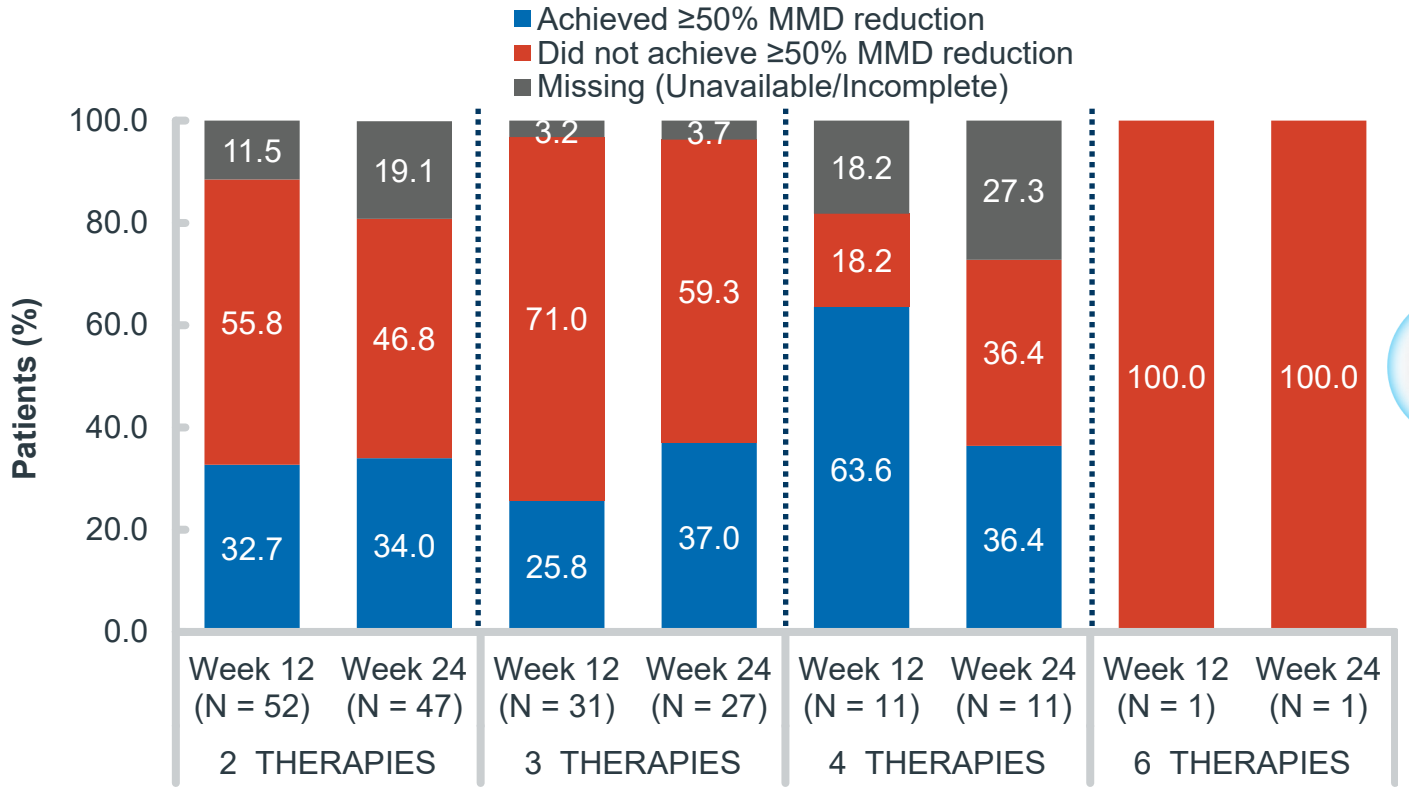


Results (Cont'd)

MMDs

- ≥50% reduction in MMD at Week 12 was achieved in 17/52 (32.7%) subjects who experienced inadequate efficacy or tolerability with two categories of prophylactic migraine therapies, 8/31 (25.8%) subjects with three categories, and 7/11 (63.6%) subjects with four categories.
- At Week 24, ≥50% reduction in MMD was observed in 16/47 (34.0%) subjects who experienced inadequate efficacy with two categories of prophylactic migraine therapies, 10/27 (37.0%) subjects with three categories, and 4/11 (36.4%) subjects with four categories (**Figure 4**).

Figure 4. Proportion of patients who achieved ≥50% MMD reduction at 12 and 24 weeks of erenumab therapy by number of previously ineffective or intolerable therapies

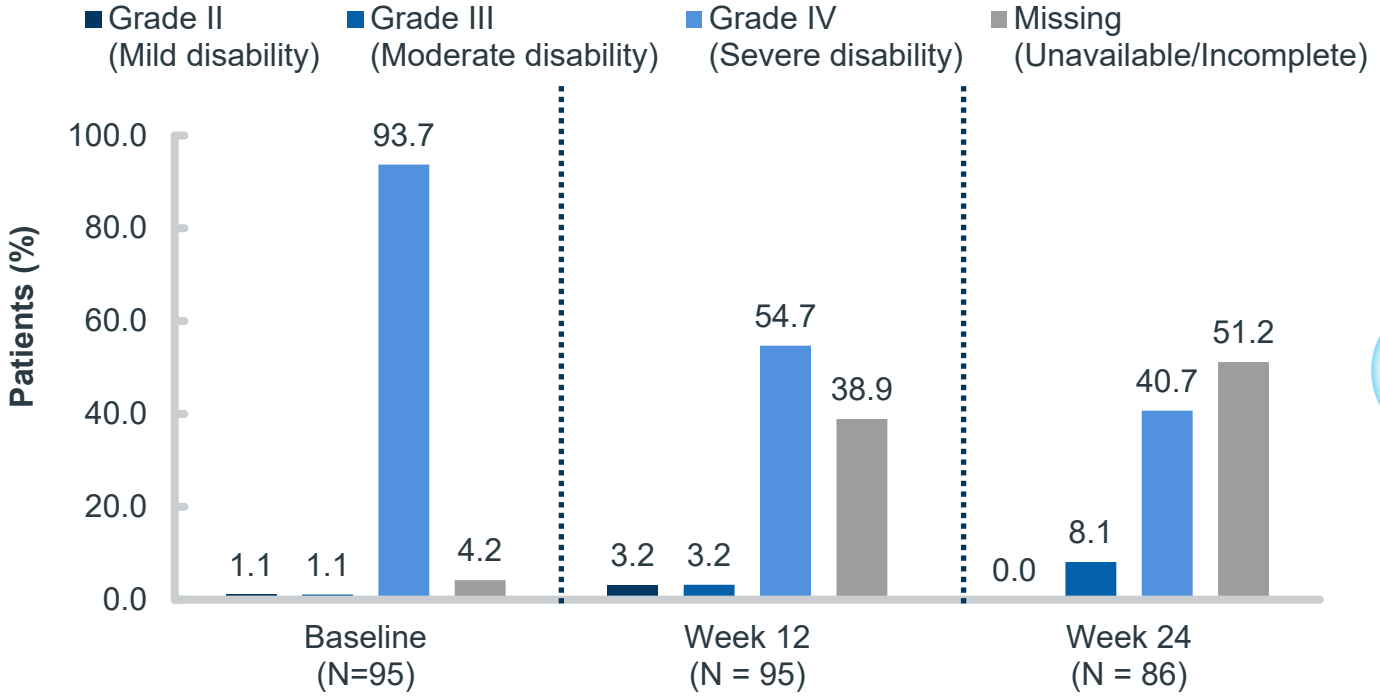


Results (Cont'd)

Improvement in MIDAS scores

- In all instances, the proportion of participants with missing data increased at follow-up timepoints.
- A reduction in the percent of subjects who reported a MIDAS score corresponding to Grade IV was observed, from 93.7% at baseline to 54.7% at Week 12 and 40.7% at Week 24 (**Figure 5**).

Figure 5. Proportion of patients reporting MIDAS scores at 12 and 24 weeks of erenumab therapy

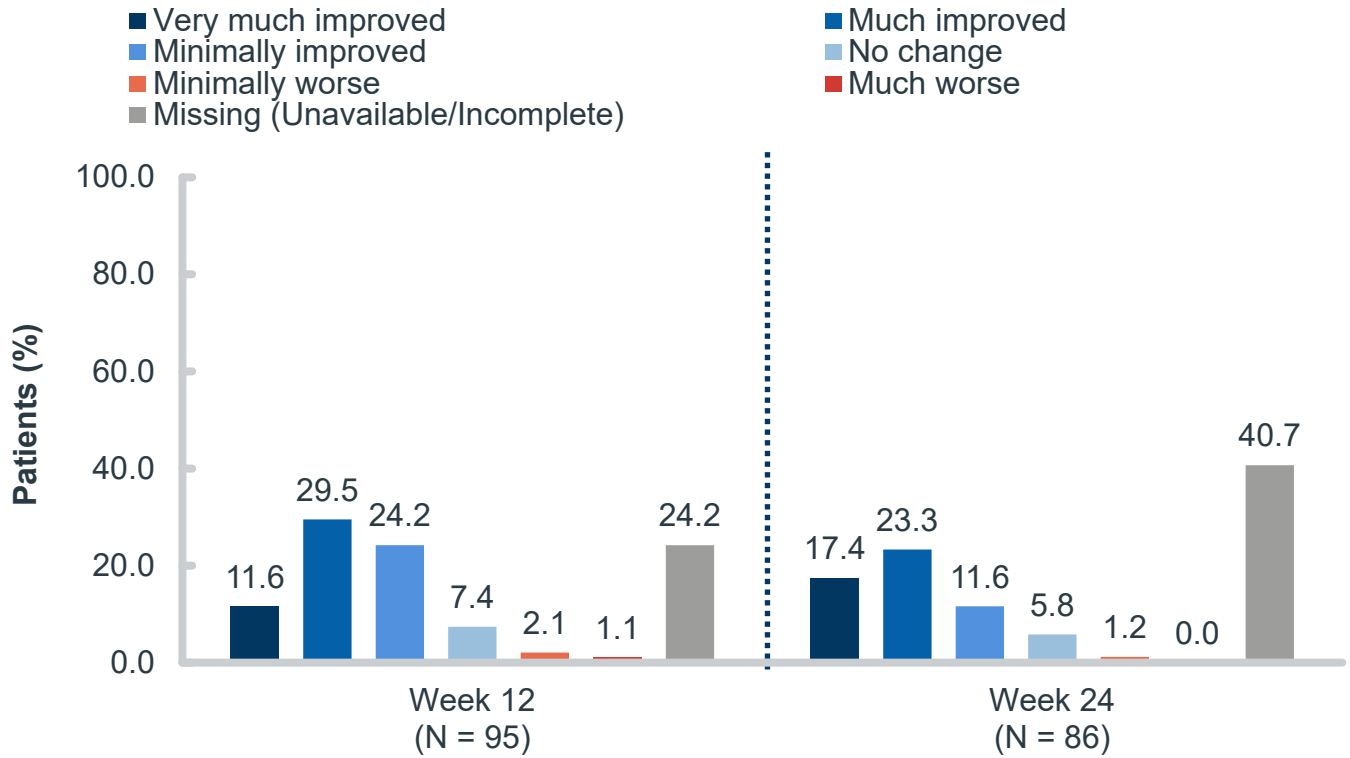


Results (Cont'd)

Improvement in P-GIC scores

- Through P-GIC, 65.3% and 52.3% of participants reported improvement in their condition at Weeks 12 and 24, respectively (**Figure 6**).

Figure 6. Proportion of patients reporting P-GIC scores at 12 and 24 weeks of erenumab therapy

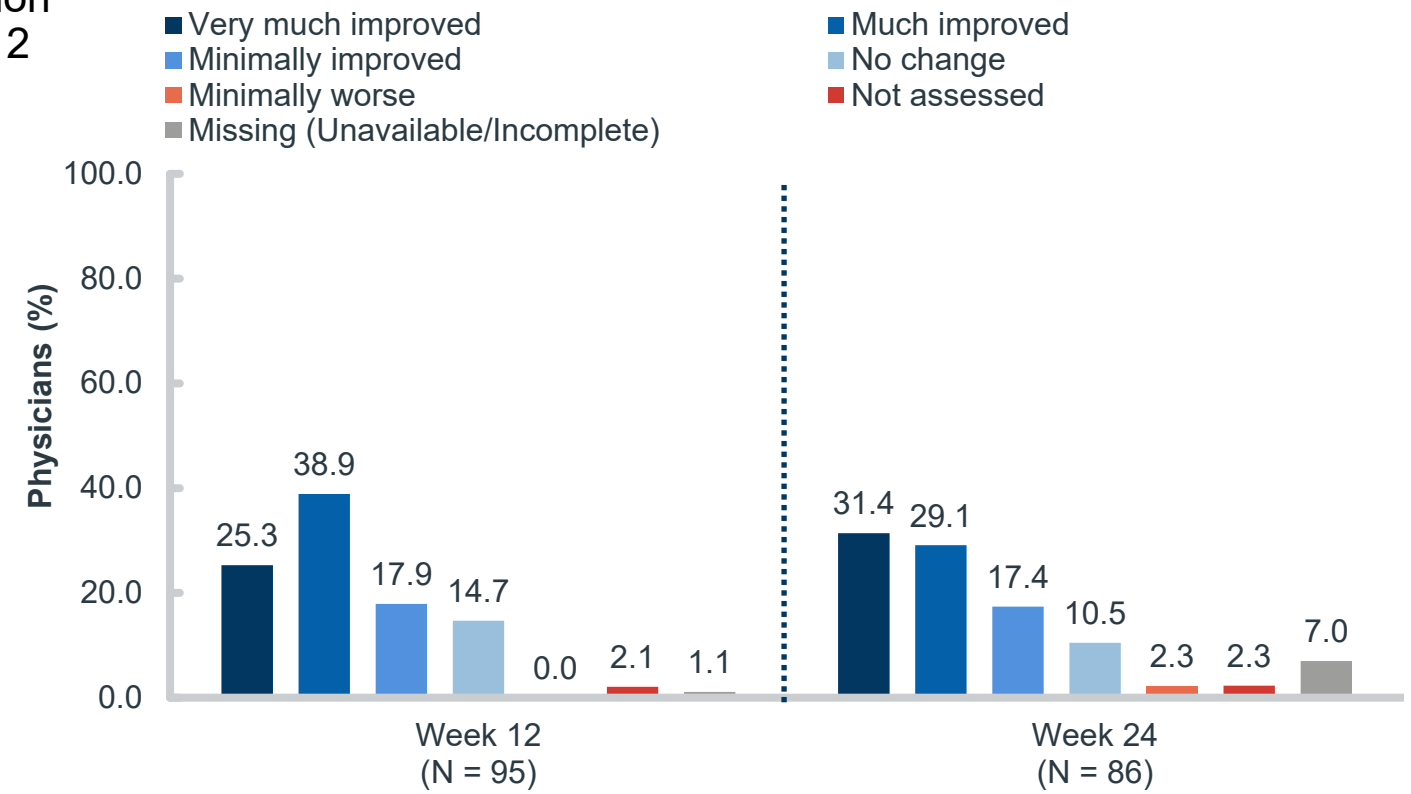


Results (Cont'd)

Improvement in CGI-I scores

- Physicians reported improvement in the condition of 82.1% and 77.9% of participants at Weeks 12 and 24, respectively, using CGI-I (**Figure 7**).

Figure 7. Proportion of physicians reporting CGI-I scores at 12 and 24 weeks of erenumab therapy



Results (Cont'd)

Erenumab Safety

- Erenumab was generally safe and well tolerated.
- Overall, 34 adverse events (AEs) were reported in 23 participants (24.0%). No severe AEs were reported, and most AEs (88.2%) were assessed as mild. No action was taken for 67.7% of AEs, and 22 (64.7%) AEs were considered to have a suspected causal relationship with erenumab.

Table 3. Summary of adverse events

	All AEs		SAEs	
	Participants (N=96)*	Events (N=34)	Participants (N=96)*	Events (N=1)
Presence of any AE, n (%)	23 (24.0)	34 (100.0)	1 (1.0)	1 (100.0)
Severity, n (%)				
Mild	20 (20.8)	30 (88.2)	1 (1.0)	1 (100.0)
Moderate	3 (3.1)	3 (8.8)	0 (0.0)	0 (0.0)
Number of Missing	1 (1.0)	1 (2.9)	0 (0.0)	0 (0.0)
Action taken with erenumab drug, n (%)				
Concomitant drug taken	4 (4.2)	7 (20.6)	1 (1.0)	1 (100.0)
Erenumab permanently discontinued due to this adverse event	3 (3.1)	3 (8.8)	0 (0.0)	0 (0.0)
No action taken	16 (16.7)	23 (67.7)	0 (0.0)	0 (0.0)
Non-drug therapy given	1 (1.0)	1 (2.9)	0 (0.0)	0 (0.0)
Outcome of the subject/adverse event, n (%)				
Completely recovered	11 (11.5)	18 (52.9)	1 (1.0)	1 (100.0)
Condition improving	7 (7.3)	7 (20.6)	0 (0.0)	0 (0.0)
Condition still present and unchanged	7 (7.3)	9 (26.5)	0 (0.0)	0 (0.0)

* One subject received erenumab before the end of the screening period and was therefore not eligible for this study. However, this subject was included in the safety analyses.

Results (Cont'd)

Erenumab Safety (Cont'd)

- One mild case of rectal hemorrhage was reported as an SAE and suspected to have a causal relationship with erenumab. This SAE was resolved by the time of study end and the subject completely recovered without sequelae (**Table 3**).

Table 3. Summary of adverse events (Cont.)

	All AEs		SAEs	
	Participants (N=96)*	Events (N=34)	Participants (N=96)*	Events (N=1)
Presence of any AE, n (%)	23 (24.0)	34 (100.0)	1 (1.0)	1 (100.0)
Subject recovered with sequelae, n (%)				
No	9 (9.4)	15 (83.3)	1 (1.0)	1 (100.0)
Yes	2 (2.1)	2 (11.1)	0 (0.0)	0 (0.0)
Number of Missing	1 (1.0)	1 (5.6)	0 (0.0)	0 (0.0)
Assessment of causality to erenumab, n (%)				
Not suspected	9 (9.4)	12 (35.3)	0 (0.0)	0 (0.0)
Suspected	15 (15.6)	22 (64.7)	1 (1.0)	1 (100.0)
AE Seriousness Assessment, n (%)				
Other Seriousness Criteria	1 (1.0)**	-	1 (1.0)**	-

* One subject received erenumab before the end of the screening period and was therefore not eligible for this study. However, this subject was included in the safety analyses.
** One mild case of rectal hemorrhage was reported as an SAE.

Conclusions

- Erenumab treatment was safe and generally well tolerated among patients with previous ineffective prophylactic migraine therapy experience.
- One third of real-world migraine patients previously experienced inadequate effectiveness or tolerability with two to six categories of prophylactic migraine therapies achieved ≥50% MMD reduction after three months of erenumab treatment.
- Erenumab therapy was associated with patient-reported improvement in migraine clinical status and disability score as assessed by study subjects using P-GIC and MIDAS. Physicians also reported migraine improvement using CGI-I.
- MAGIC provided real-world evidence of erenumab effectiveness, safety, and usage for migraine prevention in adult Canadian patients with multiple prior ineffective prophylactic treatments.

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