REVIEW

Efficacy and Safety of Galcanezumab for the Preventive Treatment of Migraine: A Narrative Review

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ABSTRACT

Migraine is a debilitating neurologic disease. People who experience migraine can have substantial disability, impaired functioning and a decreased quality of life (QoL). Expert recommendations suggest that people with frequent migraine attacks or severe impairment related to attacks may benefit from preventive treatment. Despite these recommendations and the existence of evidence-based guidelines for the use of preventive medication, many people who are candidates for preventive therapies do not receive them. Thus, there is still a substantial unmet need for preventive migraine treatment. Calcitonin gene-related peptide (CGRP) has a demonstrated role in the pathophysiology of migraine. Galcanezumab-gnlm (galcanezumab)
is a humanized monoclonal antibody that binds to the CGRP ligand and prevents binding to its receptor. It is administered as a once-monthly subcutaneous injection. The aim of this review is to present a comprehensive overview of the existing short- and long-term efficacy and safety data for galcanezumab in patients with migraine. Data from the phase 3, randomized, double-blind, placebo-controlled EVOLVE-1, EVOLVE-2 and REGAIN studies show that galcanezumab treatment for 3 or 6 months results in overall reduction in mean monthly migraine headache days in patients with episodic (EVOLVE-1 and EVOLVE-2) and chronic (REGAIN) migraine. Greater proportions of patients with episodic migraine receiving galcanezumab versus placebo demonstrated a $\geq 50\%$, $\geq 75\%$ and 100% response to therapy and reported a lower level of disability and an improvement in functioning and QoL. Similarly, when compared with placebo, greater proportions of patients with chronic migraine treated with galcanezumab demonstrated a $\geq 50\%$ and $\geq 75\%$ response and reported improved functioning. A 12-month open-label study demonstrated the continued efficacy of galcanezumab for up to 12 months. In all studies galcanezumab was well tolerated. In conclusion, data from pivotal studies show that galcanezumab may fulfill an unmet need in the treatment of patients with migraine who require preventive therapy.

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PLAIN LANGUAGE SUMMARY

Migraine is a significant contributor to the global burden of disease. Migraine symptoms can lead to substantial disability and can significantly impact an individual's ability to perform everyday tasks and their overall quality of life. While individuals with infrequent migraine attacks might have success with acute treatments alone, those with more frequent attacks or who have severe migraine-related impairment may require preventive treatment. Although recommendations on the use of preventive treatment exist, only about one-third of individuals who qualify for preventive therapy actually receive it, resulting in a substantial unmet need. Calcitonin gene-related peptide (CGRP) has a demonstrated role in migraine. Galcanezumab is a humanized monoclonal antibody that binds to the CGRP ligand and prevents receptor binding. In clinical trials of patients with ≥ 4 migraine headache days per month, treatment with galcanezumab was associated with a reduction in the average number of migraine headache days per month. The majority of galcanezumab groups had greater responder rates compared with the placebo groups, and levels of disability and daily functioning were generally improved. Galcanezumab was well tolerated, with the most common adverse events being injection site reactions. The results from the clinical trials of galcanezumab suggest that this drug may fulfill an unmet need in the treatment of individuals with migraine who require preventive therapy.

Keywords: CGRP antagonists; Chronic migraine; Episodic migraine; Galcanezumab; Migraine; Migraine prevention

Key Summary Points

Individuals who experience migraine can have a high level of disability and substantial impairments in functioning and quality of life (QoL), and there remains a substantial unmet need in these individuals.

In clinical trials of up to 12 months' duration, galcanezumab reduced the number of mean monthly migraine headache days from baseline compared with placebo in patients with episodic and chronic migraine.

Compared with placebo, more patients receiving galcanezumab responded to treatment.

Patients with episodic migraine receiving galcanezumab reported a lower level of disability and an improvement in functioning and QoL compared with placebo, while patients with chronic migraine reported improved functioning.

Galcanezumab was well tolerated in clinical trials, and these efficacy and safety results suggest that galcanezumab may fulfill an unmet need in the treatment of people with migraine who require preventive therapy.

INTRODUCTION

Migraine is a chronic neurologic disorder leading to substantial disability, impaired functioning and decreased quality of life (QoL) [1]. Migraine-related anxiety and lifestyle compromises between migraine attacks also impact QoL in many individuals [2]. Migraine is a significant contributor to the global burden of disease and was the second leading cause of disability in 2016 [3]. Notably, migraine is the leading cause of disability in individuals under 50 years of age, potentially impacting

education, relationships and career prospects [4]. Patients who experience migraine on < 15 days per month are considered to have episodic migraine, whereas those with more frequent migraine are considered to have chronic migraine. The International Headache Society classifies headaches occurring on ≥ 15 days per month, of which ≥ 8 are migraine headache days (MHDs), for at least 3 months as chronic migraine [5, 6]. Chronic migraine is associated with a substantially greater level of disability than episodic migraine [7].

Individuals with infrequent migraine attacks can often manage them with acute treatments, but preventive treatment may be needed if attacks are more frequent or result in severe impairment [8]. An expert panel in the 2007 American Migraine Prevalence and Prevention (AMPP) study recommended that MHDs and migraine-associated level of impairment should be used to identify people to whom preventive treatment should be offered (Fig. 1) [9]. Evidence-based guideline recommendations include anti-epileptic drugs, beta blockers and some anti-depressants for the prevention of episodic and chronic migraine, while onabotulinumtoxinA is recommended for the prevention of chronic migraine only [10, 11]. Notably, the American Headache Society emphasizes the use of evidence-based preventive treatment whenever possible and appropriate [6].

Despite these recommendations, persons with migraine often do not take existing preventive therapies. The AMPP study estimated that 38% of people with migraine met the criteria to be offered preventive therapy, but only 13% reported using it [9]. In a more recent survey of 21,143 patients with migraine, around 25% of patients meeting criteria to be offered preventive treatment reported ever taking a preventive medication [12]. Lack of patient awareness of disease management and low compliance with prescribed therapy can contribute to this disparity [9]. Low adherence and early discontinuation of preventive treatment can be attributed to delayed onset of effect with the need for medication titration, adverse side effects [13, 14] and a gradual loss of efficacy over time [15]. This suggests there is still a
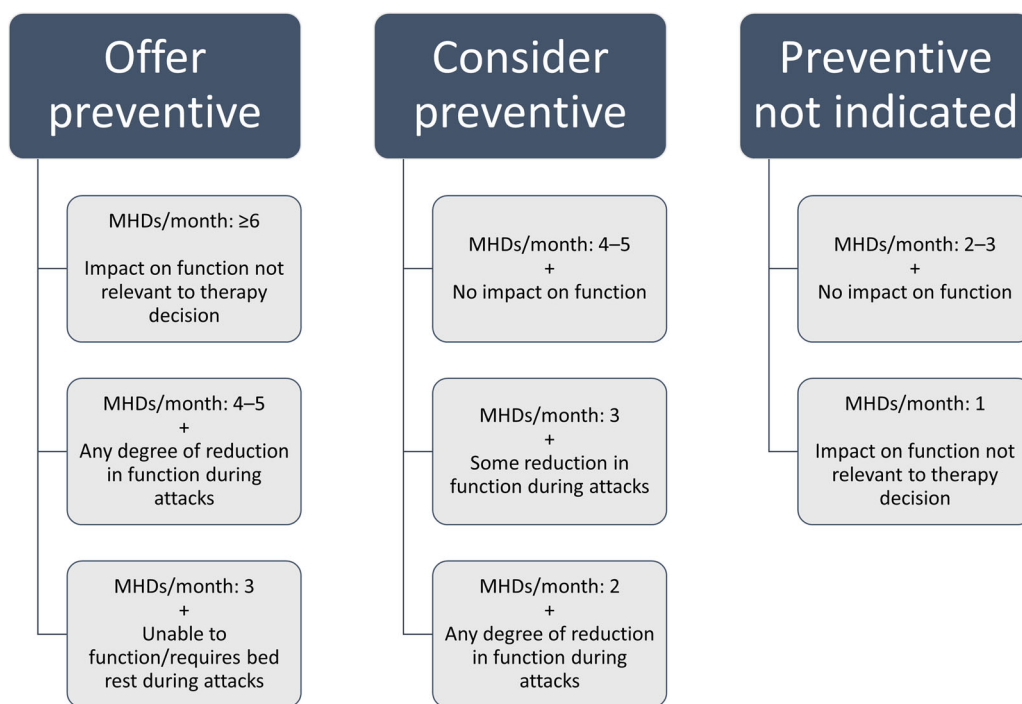

Fig. 1 The American Migraine Prevalence and Prevention study recommendations for preventive treatment [9]. *MHDs* migraine headache days

substantial unmet need for preventive migraine treatment.

Focus is increasing on the role of calcitonin gene-related peptide (CGRP) in migraine [16–19]. CGRP is a neuropeptide produced throughout the central nervous system, including the peripheral sensory neurons. One of its many functions involves pain perception via activation of the trigeminal neurons [16–19]. The release of CGRP is known to increase during migraine attacks [18]. The infusion of CGRP in patients with migraine can induce migraine-like attacks, and CGRP levels have been shown to decrease after administration of acute treatments for migraine [17], suggesting a role for CGRP in migraine [20].

Galcanezumab-gnlm (galcanezumab) is a humanized monoclonal antibody that binds to the CGRP ligand and prevents binding to its receptor. It is administered as a once-monthly subcutaneous injection and has been shown to be effective in several short-term ($\leq$ 6 months) phase 2 [21–23] and phase 3 [24–26] studies in patients with episodic or chronic migraine. In addition, a long-term 12-month open-label study in patients with episodic or chronic migraine has demonstrated the continued safety and efficacy of galcanezumab [27]. The aim of this review is to present a comprehensive overview of the existing short- and long-term efficacy and safety data for galcanezumab in patients with migraine. This article is based on previously conducted studies and does not contain any studies with human participants or animals performed by any of the authors.

PIVOTAL STUDIES OF GALCANEZUMAB

The efficacy and safety of galcanezumab in the prevention of migraine was evaluated in four phase 3 clinical trials: EVOLVE-1, EVOLVE-2, REGAIN and a long-term open-label safety study. EVOLVE-1 and -2 were multicenter, randomized, double-blind, placebo-controlled trials in which galcanezumab was administered to patients with episodic migraine (4–14 MHDs per month) as: (1) a 240-mg loading dose followed by 120 mg monthly for a total of 6 months or

(2) 240 mg monthly for 6 months [25, 26]. REGAIN was also a multicenter, randomized, double-blind, placebo-controlled design and used the same galcanezumab dosage regimens as EVOLVE-1 and -2, but it was a 12-month study (3-month double-blind period plus 9-month open-label period not reported herein) conducted in patients with chronic migraine ($\geq$ 15 headache days per month of which $\geq$ 8 were MHDs) [24]. The long-term, open-label safety study investigated the safety, tolerability and efficacy of galcanezumab using the same dose regimens as the EVOLVE and REGAIN studies for up to 12 months in patients with episodic or chronic migraine [27].

Full details of these studies can be found in the primary publications [24–27].

OVERVIEW OF KEY DATA FROM THE EVOLVE-1, EVOLVE-2 AND REGAIN STUDIES

Efficacy in Episodic Migraine

The results for EVOLVE-1 and EVOLVE-2 were adjusted for multiplicity, and all primary and key secondary end points met the criteria for statistical significance. The EVOLVE studies demonstrated that galcanezumab treatment was superior to placebo in terms of reducing the mean number of monthly MHDs in patients with episodic migraine over a 6-month treatment period [25, 26]. Compared with placebo, both the galcanezumab 120 mg and 240 mg treatment groups had significantly reduced mean monthly MHDs over the 6-month treatment period, with significant improvements versus placebo seen as early as 1 month into treatment (Table 1). The overall reductions in mean monthly MHDs with galcanezumab 120 mg and 240 mg versus placebo over the 6-month treatment period are presented in Fig. 2. The mean numbers of MHDs with acute medication use were also significantly reduced with galcanezumab 120 mg and 240 mg versus placebo ($p < 0.001$).

Studies on patient preferences for migraine prevention show that a $\geq$ 50% improvement in

Table 1 Reduction in mean monthly migraine headache days over 6 months with galcanezumab or placebo in: (a) EVOLVE-1, (b) EVOLVE-2 and (c) REGAIN [24–26]. In all studies, patients in the galcanezumab 120 mg group received a 240-mg loading dose at their first dosing visit

	EVOLVE-1			EVOLVE-2			REGAIN		
	Placebo	GALCA 120 mg	GALCA 240 mg	Placebo	GALCA 120 mg	GALCA 240 mg	Placebo	GALCA 120 mg	GALCA 240 mg
N	433	213	212	461	231	223	558	278	277
Baseline mean MHDs, days	9.1	9.2	9.1	9.2	9.1	9.1	19.6	19.4	19.2
LSM change from BL in monthly MHDs (SE)									
Month 1									
N	422	210	208	450	225	219	535	273	270
Change from BL	− 1.67 (0.26)	− 3.72 (0.32)**	− 3.59 (0.32)**	− 1.17 (0.22)	− 3.90 (0.29)**	− 3.23 (0.30)**	− 1.78 (0.36)	− 4.06 (0.44)**	− 4.22 (0.43)**
Month 2									
N	403	199	199	424	217	217	514	264	268
Change from BL	− 2.54 (0.26)	− 4.39 (0.33)**	− 4.35 (0.33)**	− 2.16 (0.23)	− 4.01 (0.29)**	− 3.76 (0.30)**	− 3.04 (0.38)	− 5.01 (0.47)**	− 4.51 (0.47)*
Month 3									
N	381	194	191	402	213	216	498	256	262
Change from BL	− 2.99 (0.27)	− 4.67 (0.34)**	− 4.45 (0.34)**	− 2.19 (0.23)	− 3.81 (0.30)**	− 4.49 (0.30)**	− 3.39 (0.40)	− 5.41 (0.50)**	− 5.12 (0.50)**
Month 4									
N	369	189	185	397	208	208	–	–	–
Change from BL	− 3.19 (0.28)	− 5.11 (0.35)**	− 4.53 (0.35)**	− 2.42 (0.24)	− 4.51 (0.31)**	− 4.32 (0.32)**	–	–	–
Month 5									
N	358	180	176	384	199	198	–	–	–

Table 1 continued

	EVOLVE-1			EVOLVE-2			REGAIN		
	Placebo	GALCA 120 mg	GALCA 240 mg	Placebo	GALCA 120 mg	GALCA 240 mg	Placebo	GALCA 120 mg	GALCA 240 mg
Change from BL	− 3.11 (0.28)	− 5.37 (0.35)**	− 5.21 (0.35)**	− 2.88 (0.23)	− 4.94 (0.29)**	− 4.70 (0.30)**	–	–	–
Month 6									
N	342	177	171	382	196	192	–	–	–
Change from BL	− 3.38 (0.28)	− 5.16 (0.35)**	− 5.30 (0.36)**	− 2.85 (0.24)	− 4.59 (0.32)**	− 4.56 (0.32)**	–	–	–

BL baseline, GALCA galcanezumab, LSM least squares mean, MHDs migraine headache days, SE standard error

$*p < 0.01$; $**p < 0.001$ versus placebo

migraine headache frequency is highly valued among patients with migraine [28, 29]; this is a clinically relevant end point in clinical trials [30]. Significantly greater proportions of patients receiving galcanezumab versus placebo over 6 months demonstrated a ≥ 50%, ≥ 75% and 100% response (defined as the percentage of patients on average in any given month with at least a 50% or 75% reduction in MHD from baseline or a 100% reduction in any given month [no MHDs]) (Fig. 3a–c) [25, 26]. Of note, there was no clear additional benefit from the 240 mg maintenance dose over the 120 mg dose with regard to reduction in MHDs.

Patients' degree of disability and the functional impact of migraine were assessed using the Migraine Disability Assessment (MIDAS) and Migraine Specific Quality of Life Questionnaire (MSQ) Version 2.1 instruments, respectively [31]. The Role Function-Restrictive (RF-R) domain of the MSQ is specifically related to the reduction in daily activities associated with migraine attacks, whereas MIDAS was designed to quantify headache-related disability over the most recent 3 months [31]. Improvements in these patient-reported outcomes are reflected as a decrease in MIDAS total score and an increase in MSQ score [31]. In the EVOLVE studies, MIDAS was measured at baseline, 3 and 6 months, and MSQ RF-R was measured monthly. Use of galcanezumab resulted in a mean change from baseline in both these measures, with improvements for galcanezumab treatment groups versus the placebo group in the MIDAS total score at month 6 (Fig. 4a) and the least squares mean of months 4–6 in MSQ RF-R (Fig. 4b) [25, 26].

Efficacy in Chronic Migraine

In REGAIN, the primary and key secondary analyses were adjusted for multiplicity; only results that remained statistically significant after this adjustment are described as significant here. Compared with placebo, patients with chronic migraine receiving galcanezumab 120 mg or 240 mg for 3 months in REGAIN had significant reductions in mean monthly MHDs over the 3-month treatment period, seen as
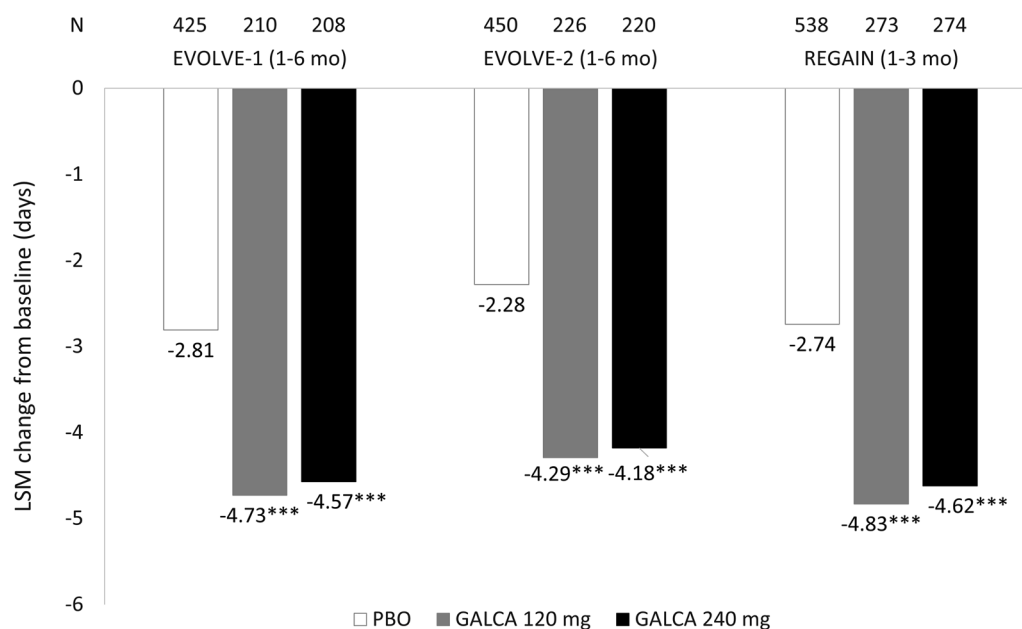
Fig. 2 Reduction in mean monthly migraine headache days in the overall study period in the EVOLVE-1, EVOLVE-2 and REGAIN studies [24–26]. ***p < 0.001 versus placebo. *GALCA* galcanezumab, *LSM* least squares mean, *mo* months, *PBO* placebo. In all studies, patients in the galcanezumab 120 mg group received a 240-mg loading dose at their first dosing visit

early as 1 month (Table 1) [24]. The reductions in mean monthly MHDs with galcanezumab 120 mg and 240 mg versus placebo are presented in Fig. 2. Regarding reductions in mean monthly MHDs with acute medication use, only the reduction in the galcanezumab 240 mg group was significantly greater than placebo ($p < 0.001$); the reduction with galcanezumab 120 mg was nominally greater than placebo (nominal p value < 0.001). There were no statistical differences between doses on any efficacy measure.

Compared with placebo, the proportions of patients responding to treatment were significantly greater with both galcanezumab 240 mg ($\geq 50\%$ and $\geq 75\%$ response) and galcanezumab 120 mg ($\geq 50\%$ response) (Fig. 3a, b) [24]. The number of patients achieving a 100% response in REGAIN was very small (< 2% in all treatment groups) and was not significantly different for galcanezumab versus placebo (Fig. 3c) [24].

In REGAIN, the MIDAS score was measured at baseline and 3 months, and the MSQ RF-R was measured monthly. Galcanezumab 120 mg

or 240 mg improved the MSQ RF-R score to a greater degree than placebo at 3 months (Fig. 4b). Galcanezumab 120 mg demonstrated a greater mean improvement in MIDAS total score; however, the improvement with the galcanezumab 240 mg dose was not different from placebo at 3 months (Fig. 4a) [24].

Safety

The proportion of patients experiencing at least one treatment-emergent adverse event (TEAE) was 60.4–67.7% in EVOLVE-1, 62.3–71.5% in EVOLVE-2 and 50.0–58.2% in REGAIN. The TEAEs reported as $\geq 3\%$ in at least one galcanezumab treatment arm in the EVOLVE and REGAIN studies are presented in Fig. 5 [24–26]. Injection-site pain was the most commonly reported TEAE overall. TEAEs that differed from placebo across all three studies include injection site pruritis and injection site reaction with a greater frequency observed in the galcanezumab 240 mg treatment group (Fig. 5).

No deaths were reported in any of the studies, and serious AEs were reported in $\leq 3.1\%$ of
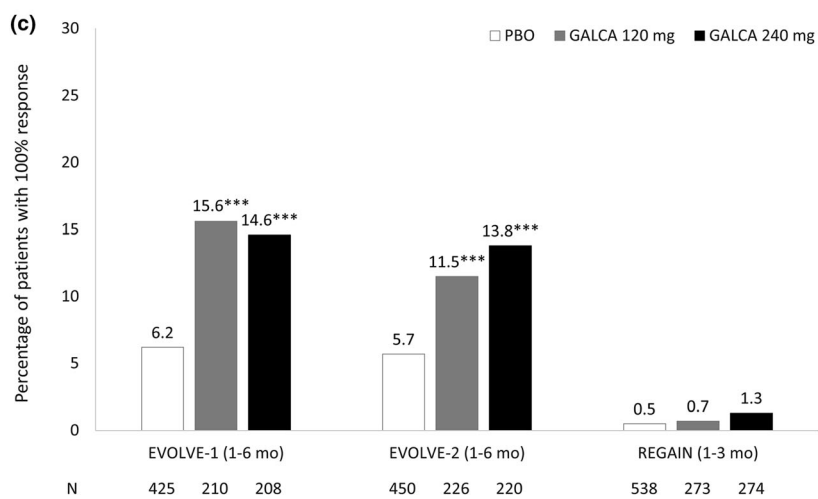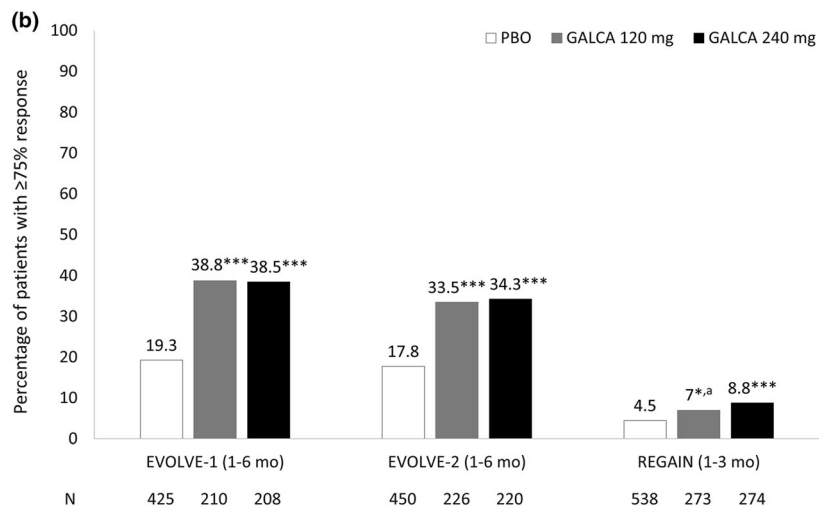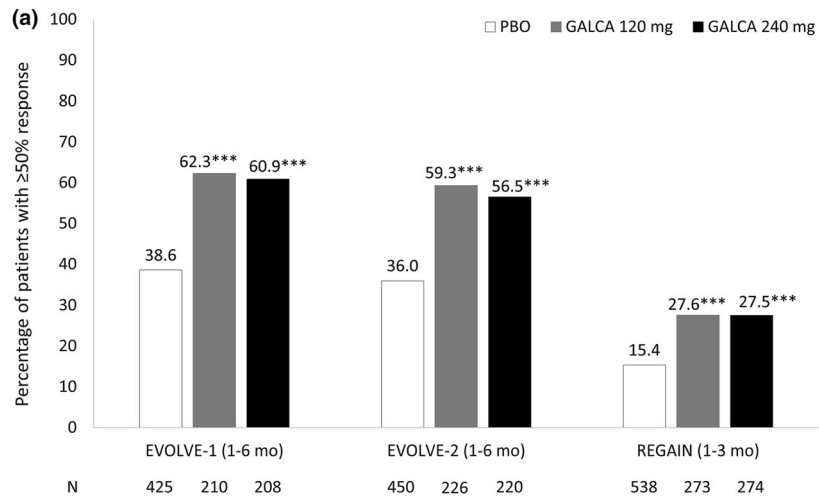
◄ **Fig. 3** Rate of response to galcanezumab in the overall study period in the EVOLVE-1, EVOLVE-2 and REGAIN studies [24–26]. **a** ≥ 50% response; **b** ≥ 75% response; **c** 100% response. $^*p < 0.05$; $^{***}p < 0.001$ vs. placebo. ^{a}Not significant after adjustment for multiplicity. *GALCA* galcanezumab, *PBO* placebo. In all studies, patients in the galcanezumab 120 mg group received a 240-mg loading dose at their first dosing visit

patients. The rates of discontinuation due to AEs were low across the three studies (≤ 4.1%) [24–26, 32]. Overall, a greater number of patients in the galcanezumab groups than the placebo groups reported TEAEs [24–26]. No cardiovascular events were reported in the EVOLVE or REGAIN studies [24–26].

OVERVIEW OF OPEN-LABEL SAFETY STUDY OUTCOMES

Herein we report the results from a 12-month open-label study in patients with chronic and episodic migraine [27]. Patients enrolled in this study were a separate group to those participating in the EVOLVE and REGAIN studies and had no prior exposure to galcanezumab or any other CGRP antibody.

Efficacy

After 12 months of open-label treatment [27], the overall reduction from baseline in mean monthly MHDs was − 5.6 and − 6.5 days in galcanezumab 120 mg and 240 mg recipients, respectively. More than 65% of patients receiving galcanezumab had a ≥ 50% response in this study, and ≥ 75% and 100% responses were seen in at least 44% and 21% of patients, respectively [27]. These rates are similar to those seen in the short-term studies. Patient-reported outcomes had also improved from baseline to 12 months in both galcanezumab 120 mg and 240 mg groups in this study, with respect to both the MIDAS total score (least squares mean reductions: − 33.6 and − 32.7) and the MSQ RF-R (least squares mean increases: 31.6 and 33.4) [27].

Safety

TEAEs reported in the open-label study are summarized in Table 2 [27]. No deaths were reported. Similar to the EVOLVE and REGAIN studies, injection site pain and nasopharyngitis were frequently reported events, as were injection-related events (reaction, erythema, bruising). No cardiovascular events of concern were reported. There were no statistically significant differences between groups in the frequencies of TEAEs reported.

DISCUSSION

Overall, data from the pivotal studies of galcanezumab show that it is effective in patients with episodic or chronic migraine, with improvements in monthly MHDs seen as early as 1 month. Long-term data demonstrate consistent effectiveness up to 12 months for both doses. Galcanezumab is also safe, with good tolerability shown up to 12 months.

These results are consistent with those of a pooled analysis of the EVOLVE-1, EVOLVE-2 and REGAIN studies that investigated maintenance of response with galcanezumab versus placebo [33]. Although maintenance of 100% response over 3 and 6 months was not frequent in this pooled analysis of patients with episodic and chronic migraine [33], a post hoc analysis of the patients with episodic migraine who had a 100% response rate in the EVOLVE studies found that more than one-third of galcanezumab recipients who achieved a 100% response did so for at least 1 month and that more patients had a monthly 100% response in months 4–6 of the studies than in the first 3 months [34].

The majority of people with migraine disorders present to, and are managed in, the primary care setting [12, 35–37]. People with high migraine symptom severity and those with a high level of migraine-related disability are more likely to consult with a healthcare professional about migraine-specific treatments than those with less severe/disabling disease [37–40]. Despite this, many individuals who are candidates for preventive therapy do not receive
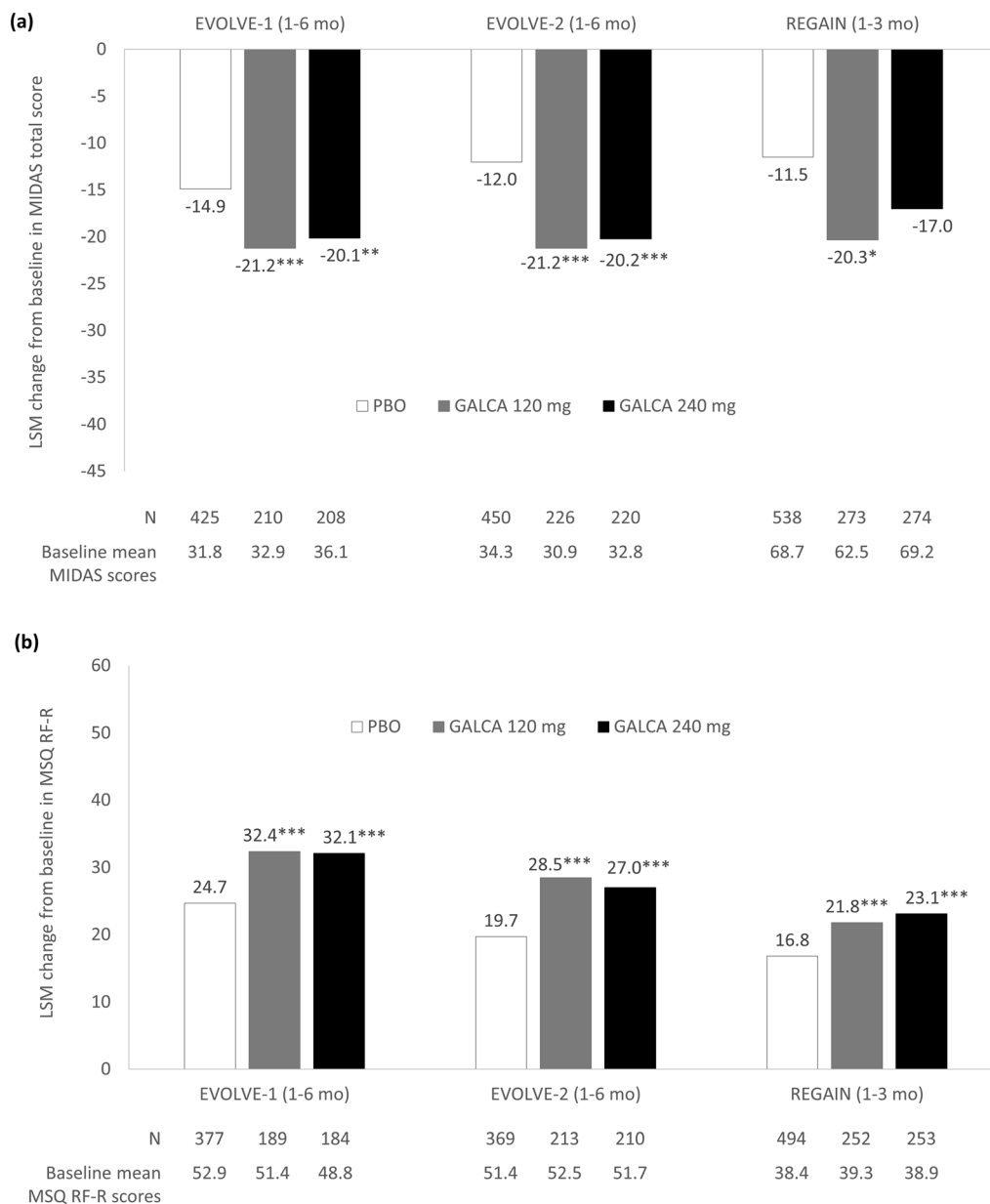
Fig. 4 Efficacy of galcanezumab on patient-reported outcomes in EVOLVE-1, EVOLVE-2 and REGAIN. **a** Change from baseline in MIDAS score; **b** change from baseline in MSQ role function-restrictive [24–26]. EVOLVE-2 data reproduced with permission [25]. $*p < 0.05$; $**p < 0.01$; $***p < 0.001$ vs. placebo. p values for all MIDAS comparisons and for galcanezumab 120 mg vs. placebo in MSQ RF-R in REGAIN are nominal. *GALCA* galcanezumab, *LSM* least squares mean, *MIDAS* Migraine Disability Assessment, *MSQ-RF-R* Migraine-specific Quality of Life Questionnaire Version 2.1 Role Function-Restrictive, *PBO* placebo. In all studies, patients in the galcanezumab 120 mg group received a 240-mg loading dose at their first dosing visit

it [9, 12, 13, 41]. A number of patient-related factors impact the use of preventive medications for migraine, including a negative attitude regarding taking medication in general, a reluctance to commit to taking daily medication for their migraine attacks, the use of
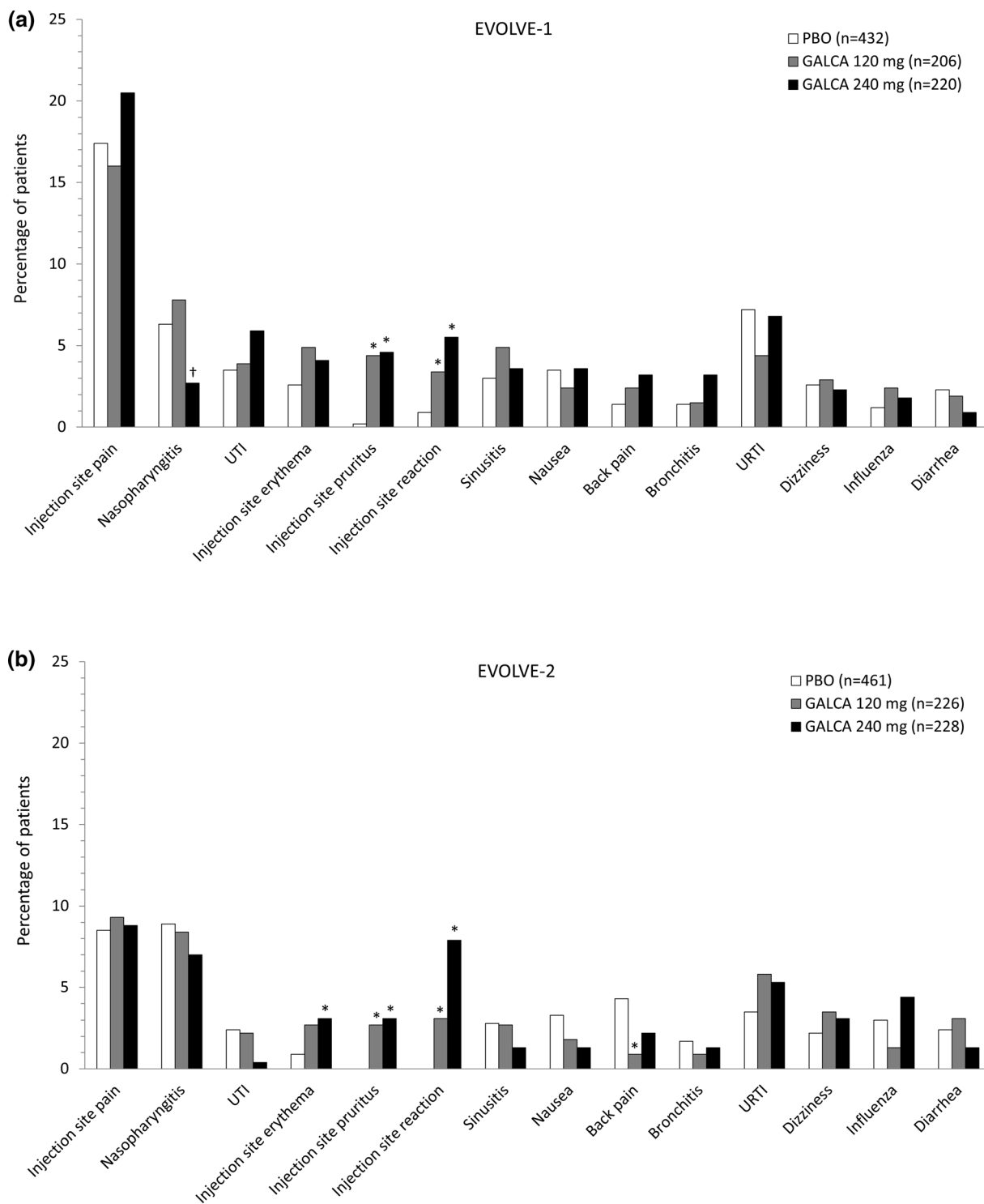
Fig. 5 Treatment-emergent adverse events occurring in ≥ 3% of patients in any galcanezumab-treated group across the **a** EVOLVE-1, **b** EVOLVE-2 and **c** REGAIN studies [24–26, 32]. $^*p < 0.05$ vs. placebo; $^†p < 0.05$ vs.

galcanezumab 120 mg. *GALCA* galcanezumab, *PBO* placebo, *URTI* upper respiratory tract infection, *UTI*, urinary tract infection
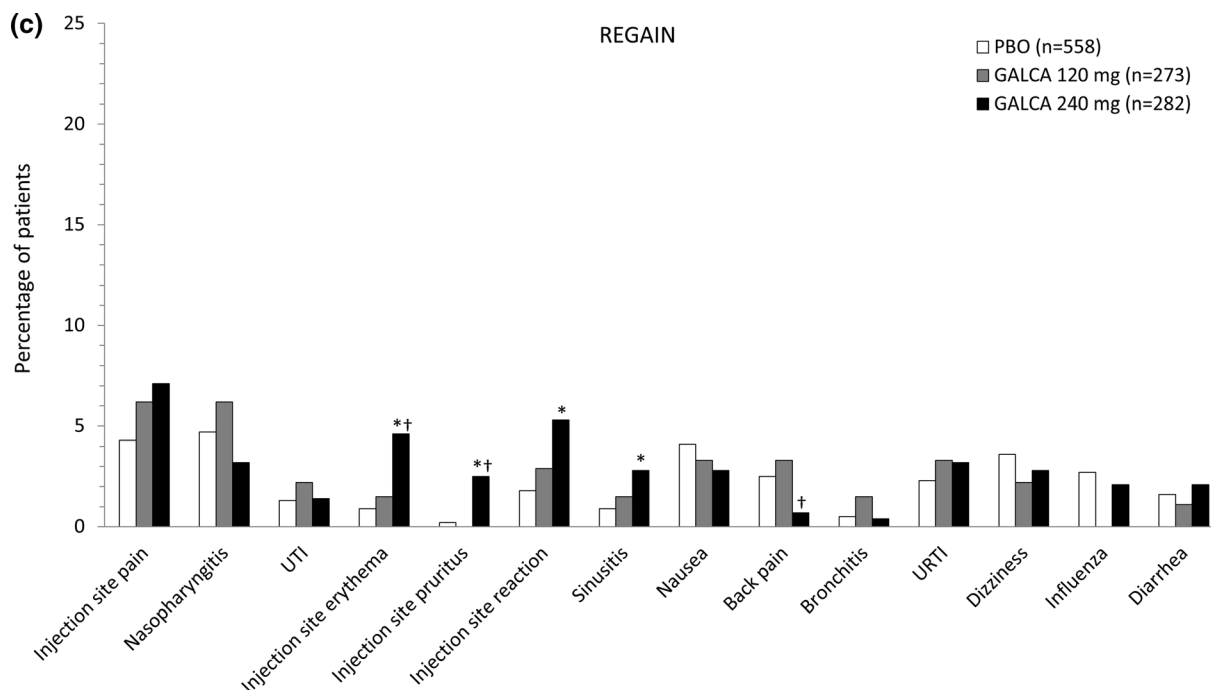
Fig. 5 continued

preventive medication in the past and a fear of drug dependency [42, 43]. Medication side effects and lack of established efficacy are also areas of concern for patients [42–44]; these are the most common self-reported reasons for discontinuing preventive medication [13].

Considering the impact that side effects can have on the long-term use of preventive medications, it is notable that discontinuations due to AEs were not frequent in the phase 3 galcanezumab studies, and the study completion rates were high (> 80%). Completion rates were similar in the placebo and galcanezumab groups in all studies [24–26]. More than 75% of patients completed 12 months of treatment in the open-label study [27]. These low rates of discontinuation may reflect the good tolerability profile of galcanezumab. As mentioned, since preventive treatment discontinuation is associated with loss of efficacy [13], the high rates of completion seen in these galcanezumab studies may also reflect patient satisfaction levels with persistence of effect through 12 months. An additional factor for the sustained efficacy seen in studies of galcanezumab may be its once-monthly administration

schedule which, in the long-term open-label study, included self-administration at home by patients or their caregivers [27]. While information is scarce for migraine, information from other studies of chronic diseases, such as osteoporosis and diabetes, highlights the higher adherence associated with medications that are administered less frequently [45, 46].

People with migraine—particularly those whose treatment is suboptimal—experience high levels of headache-related disability, poor functioning due to the impact of migraine on daily activities, depression and anxiety to a greater degree than healthy subjects [31, 40, 47–49]. A MIDAS score of ≥ 21 indicates a severe level of disability [31], and the baseline MIDAS total scores in all the studies discussed in this review ranged from 30.9 to 69.2 [24–27]. This shows that prior to galcanezumab treatment, patients included in these studies were severely disabled by their migraine attacks. Galcanezumab reduced the disability burden in patients with migraine and improved functioning, as demonstrated by changes in the MIDAS total score and the MSQ score. These results are similar to those of other studies

Table 2 Adverse events occurring in ≥ 5% of patients in any group of the open-label study [27, 32]. Reproduced under the terms of the Creative Commons Attribution 4.0 International License (http://creativecommons.org/licenses/by/4.0/)

	GALCA 120 mg (*N* = 129)	GALCA 240 mg (*N* = 141)
Overview		
Patients with ≥ 1 TEAE	106 (82.2)	121 (85.8)
Discontinuations due to AEs	6 (4.7)	7 (5.0)
Serious AEs	3 (2.3)	7 (5.0)
TEAEs		
Injection site pain	22 (17.1)	28 (19.9)
Nasopharyngitis	23 (17.8)	18 (12.8)
Upper respiratory tract infection	9 (7.0)	21 (14.9)
Injection site reaction	15 (11.6)	13 (9.2)
Back pain	12 (9.3)	15 (10.6)
Sinusitis	14 (10.9)	13 (9.2)
Nausea	10 (7.8)	9 (6.4)
Injection site erythema	9 (7.0)	9 (6.4)
Arthralgia	8 (6.2)	8 (5.7)
Influenza	8 (6.2)	8 (5.7)
Dizziness	5 (3.9)	9 (6.4)
Injection site bruising	5 (3.9)	8 (5.7)
Myalgia	8 (6.2)	3 (2.1)
Weight increased	7 (5.4)	4 (2.8)

All data shown as *N* (%)
AE adverse event, *GALCA* galcanezumab, *TEAE* treatment-emergent adverse event

which reported that the use of migraine preventives improved QoL in people with migraine [50].

CONCLUSIONS

Data from pivotal phase 3 studies show that galcanezumab is effective for the preventive treatment of migraine and has an acceptable safety profile. Galcanezumab provides a new treatment option with a novel mechanism of action to patients with migraine.

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Compliance with Ethics Guidelines. This article is based on previously conducted studies and does not contain any studies with human participants or animals performed by any of the authors.

Data availability. Data sharing is not applicable to this article as no datasets were generated or analyzed during the current study.

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