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Real-world evidence on 24 months of erenumab treatment of migraine Patients in Switzerland: Long-term data from SQUARE

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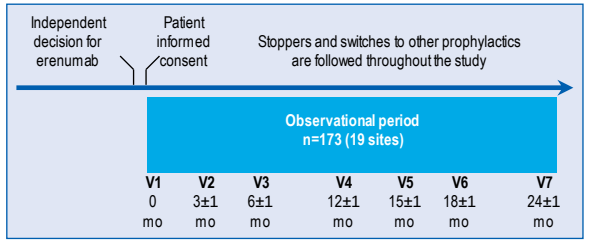
INTRODUCTION

- Erenumab, the first approved calcitonin gene-related peptide (CGRP) pathway antagonist, received marketing authorisation in Switzerland (2018) for the prevention of migraine in adults[1,2]
- Real-world data evaluating the effect of erenumab on migraine-related quality of life in patients with episodic (EM) and chronic migraine (CM) in a setting of routine medical care in Switzerland are limited
- To complement data from pivotal trials, the non-interventional observational SQUARE study (Swiss QUality of life and healthcare impact Assessment in a Real world Erenumab treated migraine population, CAMG334ACH01) aims to observe the use of erenumab in clinical practice
- Interim analyses from this study have demonstrated the effectiveness of erenumab on clinical characteristics and quality of life after 6 months of treatment, as well as the consequences of a mandatory therapy break (drug holiday) after 1 year[3,4]
- Here, we report the final results from the long-term follow-up in SQUARE spanning 24 months of treatment

METHODS

- SQUARE is a prospective, 24-month, non-interventional study. Patients with migraine who initiated erenumab (Aimovig®) in accordance with the Swiss label prior to enrolment were included in the study if they were willing and able to participate **(Figure 1)**
- Patients with prior treatment with erenumab or any CGRP pathway-based therapy or recent use of any investigational drugs were excluded
- Patients were observed over a period of 24 months

Figure 1. Study design



Key outcomes and assessments

- Outcomes included change from baseline in monthly migraine days (MMD) and achievement of at least 30%, 50%, 75% and 100% reduction in MMD, as well as change from baseline in Headache Impact Test (HIT-6™), modified Migraine Disability Assessment (mMIDAS) with a 1-month recall period, Impact of Migraine on Partners and Adolescent Children (IMPAC) scores, and acute migraine-specific medication (AMSM) days
- Variables were assessed after 6 (±1), 12 (±1), 15 (±1), 18 (±1) and 24 (±1) months.
- Safety was also assessed

Statistical analysis

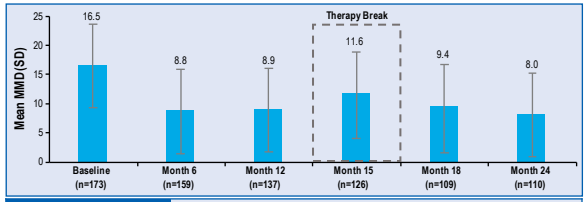
- Primarily descriptive statistics were used to evaluate the results
- All patients who received at least one dose of erenumab and for whom subsequent documentation after baseline was available were included in the evaluation

RESULTS

Demographics and baseline characteristics of the SQUARE study population

- Overall, 173 patients with EM (54%) or CM (46%) were enrolled from 19 sites, including both migraine care specialist centres and from general neurologists
- The majority of the patients were women (84.9%)
- At baseline, patients had an average of 16.6 MMD and 11.6 monthly acute medication-specific medication (AMSM) days (including triptans and ergot derivatives)
- The overall burden of migraine on patients (as measured by the number of MMD, HIT-6™ scores, mMIDAS scores, and AMSM days) and their families (IMPAC scores) decreased significantly from baseline to month 12 (i.e., before therapy break), increased at month 15 during the therapy break, and decreased again at month 18 (i.e., after therapy was restarted) and month 24 **(Figure 2-7)**

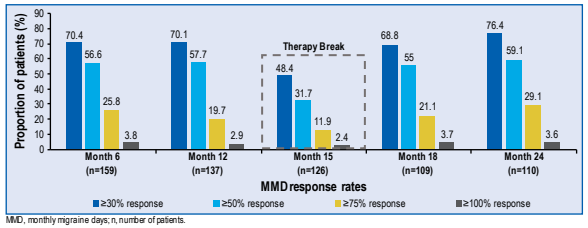
Figure 2. Effect of erenumab treatment on MMD



n	159	137	126	109	110
Change from baseline, mean (SD), days	−7.6 (7.0)	−7.7 (7.9)	−5.2 (8.2)	−7.7 (7.5)	−8.8 (7.6)

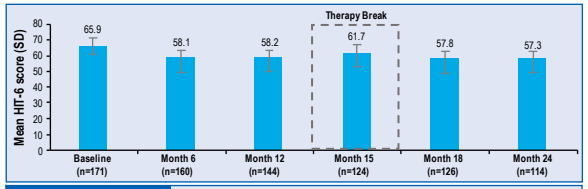
MMD, monthly migraine days; n, number of patients; SD, standard deviation.

Figure 3. Effect of erenumab treatment on MMD response rates



MMD, monthly migraine days; n, number of patients.

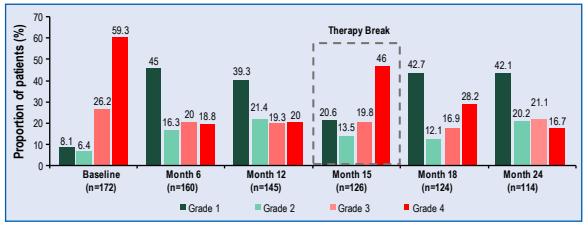
Figure 4. Effect of erenumab treatment on HIT-6™ scores



n	159	143	123	125	112
Change from baseline, mean (SD)	−7.7 (8.4)	−7.3 (8.3)	−3.7 (8.0)	−7.8 (8.6)	−8.1 (8.6)

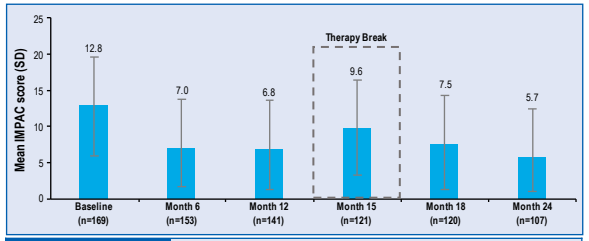
HIT-6™, Headache Impact Test; n, number of patients; SD, standard deviation.

Figure 5. Effect of erenumab treatment on mMIDAS scores



mMIDAS, modified Migraine Disability Assessment score; number of patients; SD, standard deviation

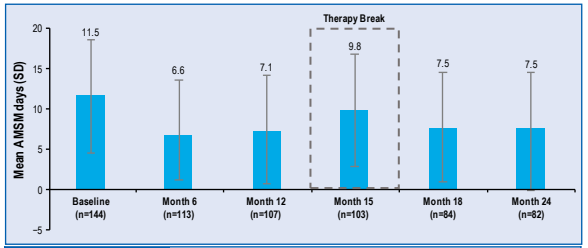
Figure 6. Effect of erenumab treatment on IMPAC scores



n	151	138	119	119	105
Change from baseline, mean (SD)	−6.1 (6.5)	−5.7 (6.6)	−2.4 (6.3)	−5.0 (6.5)	−6.5 (6.6)

IMPAC, Impact of Migraine on Partners and Adolescent Children; n, number of patients; SD, standard deviation.

Figure 7. Effect of erenumab treatment on the number of AMSM days



n	110	99	98	98	79
Change from baseline, mean (SD), days	−5.6 (5.7)	−5.2 (6.5)	−2.5 (6.6)	−2.5 (6.6)	−5.2 (6.8)

AMSM, acute medication-specific medication days; n, number of patients; SD, standard deviation.

Adverse events

- Adverse events (AEs) were reported in 84/173 patients (48.5%). Of 165 AEs reported, 97 AEs (58.8%) were suspected to be related to erenumab
- A total of 17/173 (9.8%) patients experienced at least one serious AE (SAE). None of the reported SAEs were suspected to be related to erenumab
- One death was reported and was not suspected to be related to erenumab treatment **(Table 1)**

Table 1. Patients with adverse events

AEs (MedDRA Term)	N=173
Any AE, n (%)	84 (48.5)
Any SAE, n (%)	17 (9.8)
SAEs related to erenumab	0
Death, n (%)	1 (0.6)
Deaths related to erenumab	0

AE, adverse event; n, number of patients with events; N, total number of patients in the study; SAE, serious adverse event.

CONCLUSIONS

- The SQUARE study provides one of the first prospectively collected data on treatment of migraine patients with erenumab in routine medical care in Switzerland
- A sustained reduction of MMD was observed during 12 months of continuous migraine therapy with erenumab. Subsequent interruption of erenumab was associated with a temporary increase of the migraine burden, and reduction was again seen after treatment re-initiation
- A similar trend was observed for other outcome measures (i.e. HIT-6™ score, mMIDAS score, IMPAC score and the number of AMSM days). Safety data were in accordance with the known safety profile of erenumab. No new safety signal was identified
- Overall, erenumab showed continued effectiveness and a positive safety profile over 24 months in a real-world setting in Switzerland

REFERENCES

1. Available at https://www.swissbiotech.org/listing/novartis-marks-a-new-era-for-migraine-patients-with-the-eu-approval-of-aimovig-a-first-of-its-kind-treatment-specifically-designed-for-migraine-prevention/ (last accessed on April 20, 2023).
2. Available at https://www.swissmedicinfo.ch/ViewMonographie (last accessed on May 24, 2023).
3. Schäfer E, et al. Abstract presented at the International Headache Society (IHS)– 20th International Headache Congress. 2021.
4. Gantenbein AR, et al. J Headache Pain. 2022 Nov 18;23(1):142. doi: 10.1186/s10194-022-01515-8.

DISCLOSURES

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