

# Real-world effectiveness data of erenumab-treated migraine patients in Switzerland: The SQUARE study



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Elisabeth Schäfer<sup>1</sup>, Ina Meyer<sup>1</sup>, Michael E. Arzt<sup>1</sup>, Andreas R. Gantenbein<sup>2</sup>

<sup>1</sup>Novartis Pharma Schweiz AG, Rotkreuz, Switzerland

<sup>2</sup>Department for Neurology & Neurorehabilitation, ZURZACH Care, Bad Zurzach, Switzerland

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## Background



- In 2018, erenumab received marketing authorisation in Switzerland for the prevention of migraine in adults<sup>1</sup>
- Real-world data evaluating the effect of erenumab in a setting of routine medical care in Switzerland are limited
- The observational SQUARE (Swiss QUality of life and healthcare impact Assessment in a Real-world Erenumab treated migraine population, CAMG334ACH01) study aims to address this data gap
- Here, we present the interim real-world effectiveness data of erenumab from the SQUARE study

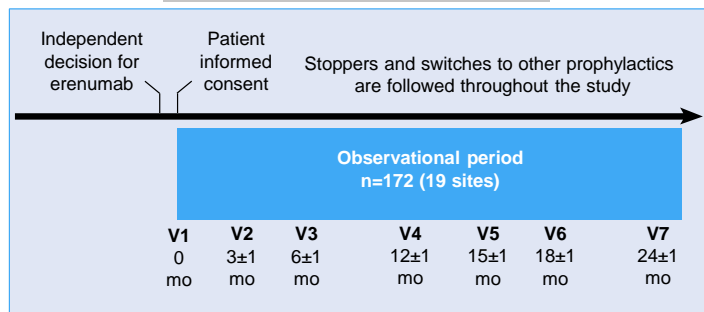
1. Data accessed from: <https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/authorisations/new-medicines/aimovig.html>, accessed on August 23, 2021.

## Methods



- SQUARE is a prospective, non-interventional study. Patients with migraine who initiated Aimovig® (erenumab) in accordance with the Swiss label prior to enrolment were included if they were willing and able to participate
- Patients with prior treatment with erenumab or any CGRP (receptor)-based therapy or recent use of any investigational drugs were excluded
- Patients were observed over a period of 24 months. Here, we present the 6-month primary analysis data

### Study design



### Primary outcome

- Change in HIT-6™ scores after 6 months post-erenumab initiation compared to baseline

### Secondary outcomes

- Change in HIT-6, mMIDAS with a 1-month recall period and IMPAC scores after 3, 6, 12, 15, 18 and 24 months compared to baseline
- Total scores on TSQM-9 after 6 months
- Change in MMDs and achievement of at least 30%, 50%, 75% and 100% reduction after 3, 6, 12, 15, 18 and 24 months compared to baseline
- Change in AMSM days after 3, 6, 12, 15, 18 and 24 months compared to baseline

Endpoints were determined a priori and not determined after review of data. The 12-, 15-, 18- and 24-month analysis will be presented later

### 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

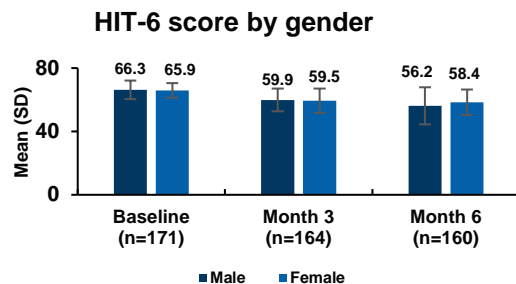
Characteristics	N=172
Age, mean (SD)	44.2 (13.9)
Gender, n (%)	
Women	146 (84.9)
Working status, n (%)	
Employed (part-time)	61 (35.5)
Employed (full-time)	54 (31.4)
Retired	14 (8.1)
Sick leave/disability insurance	11 (6.4)
In education/military service/civilian service	5 (2.9)
MMD, mean (SD)	16.6 (7.2)
Monthly acute medication days, mean (SD)	11.6 (7.0)
Type of migraine, n (%)	
EM	92 (53.8)
CM	79 (46.2)

- Overall, 172 patients were enrolled from 19 sites, including both migraine care specialist centers and general neurologists
- The majority of the patients were women
- At baseline, patients had an average of 16.6 MMDs and 11.6 monthly AMSM days
- Almost 54% of the patients fulfilled criteria for EM, and the other 46% of patients for CM

## Results

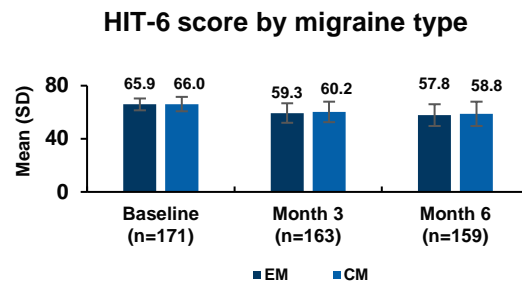


## Effect of erenumab on HIT-6 score



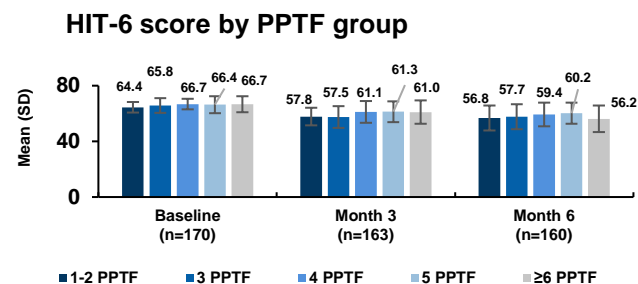
Change from baseline, mean (SD)

Visit	Male	Female
Month 3	-6.0 (6.4)	-6.3 (7.3)
Month 6	-9.7 (12.0)	-7.4 (7.6)



Change from baseline, mean (SD)

Visit	EM	CM
Month 3	-6.6 (7.6)	-5.9 (6.6)
Month 6	-8.2 (8.7)	-7.1 (8.1)



Change from baseline, mean (SD)

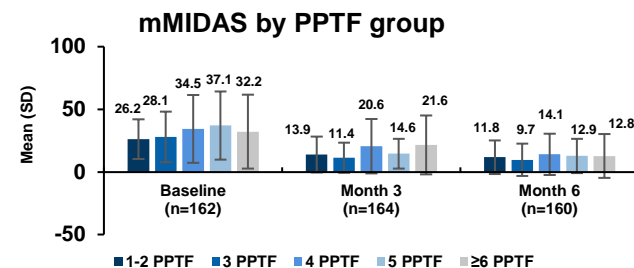
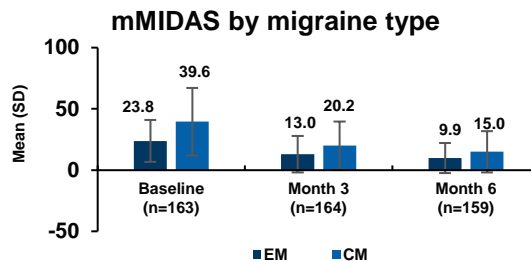
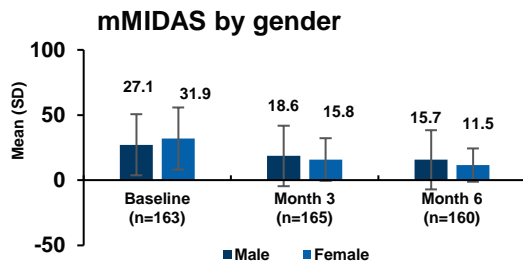
Visit	1-2 PPTF	3 PPTF	4 PPTF	5 PPTF	≥6 PPTF
Month 3	-6.8 (6.3)	-8.4 (8.7)	-5.6 (7.4)	-5.2 (6.5)	-4.4 (5.2)
Month 6	-7.8 (9.1)	-8.2 (9.3)	-7.3 (7.8)	-6.2 (7.1)	-9.2 (8.7)

- Erenumab significantly reduced HIT-6 score from baseline to Month 3 and Month 6 (WSR both  $p < 0.001$ ) in both the genders and in patients with either EM or CM
- Erenumab significantly reduced HIT-6 score in all PPTF groups from baseline to Month 3 and Month 6 (WSR all  $p < 0.001$ , except 5 PPTF BL vs. Month 3:  $p = 0.001$ )

## Results



## Effect of erenumab on mMIDAS



Change from baseline, mean (SD)

Visit	Male	Female
Month 3	-9.1 (17.7)	-15.9 (19.9)
Month 6	-9.0 (24.4)	-20.0 (21.1)

Change from baseline, mean (SD)

Visit	EM	CM
Month 3	-11.5 (15.2)	-19.0 (23.4)
Month 6	-14.1 (17.8)	-23.6 (25.1)

Change from baseline, mean (SD)

Visit	1-2 PPTF	3 PPTF	4 PPTF	5 PPTF	≥6 PPTF
Month 3	-12.2 (15.8)	-15.1 (15.4)	-15.5 (22.3)	-22.5 (23.3)	-9.6 (21.4)
Month 6	-13.1 (17.1)	-17.6 (18.7)	-20.9 (25.6)	-24.2 (23.7)	-16.7 (23.9)

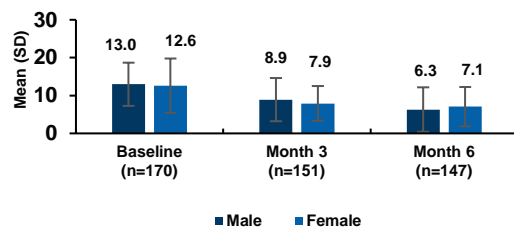
- Erenumab significantly reduced mMIDAS from baseline to Month 3 and Month 6 (WSR both  $p < 0.001$ ) in both the genders and in patients with either EM or CM
- Erenumab significantly reduced mMIDAS in all PPTF groups from baseline to Month 3 and Month 6 (WSR  $p < 0.001$  for PPTF 1-2 to 5 for Month 3 and Month 6; for  $\geq 6$  PPTF: WSR Month 3  $p = 0.025$ , Month 6  $p = 0.002$ )

## Results



## Effect of erenumab on IMPAC

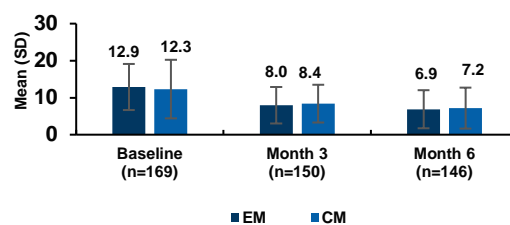
IMPAC score by gender



Change from baseline, mean (SD)

Visit	Male	Female
Month 3	-4.0 (4.4)	-5.0 (6.4)
Month 6	-6.1 (6.3)	-6.1 (6.8)

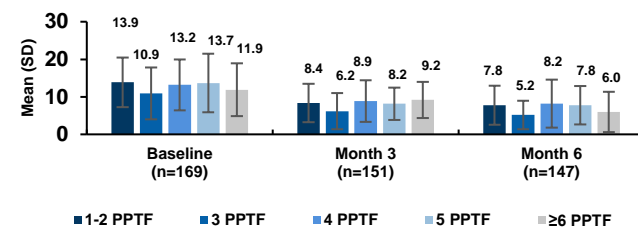
IMPAC score by migraine type



Change from baseline, mean (SD)

Visit	EM	CM
Month 3	-5.3 (5.9)	-4.2 (6.3)
Month 6	-6.5 (6.3)	-5.6 (7.1)

IMPAC score by PPTF group



Change from baseline, mean (SD)

Visit	1-2 PPTF	3 PPTF	4 PPTF	5 PPTF	≥6 PPTF
Month 3	-5.4 (5.6)	-4.7 (6.4)	-4.7 (6.9)	-5.9 (5.6)	-3.6 (5.8)
Month 6	-7.0 (6.2)	-5.8 (6.3)	-5.3 (6.4)	-6.0 (8.0)	-7.1 (7.2)

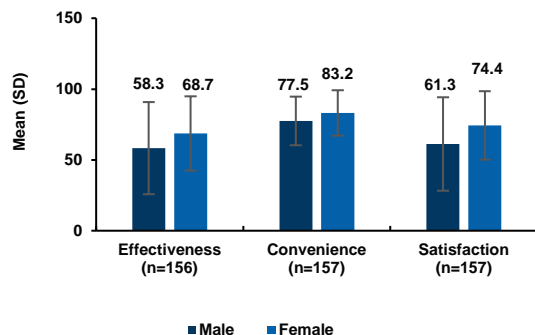
- Erenumab significantly reduced IMPAC score from baseline to Month 3 and to Month 6 (WSR both  $p < 0.001$ ) in both genders and patients with either EM or CM
- Erenumab significantly reduced IMPAC score in all PPTF groups from baseline to Month 3 and Month 6 (WSR  $p \leq 0.004$ )

## Results

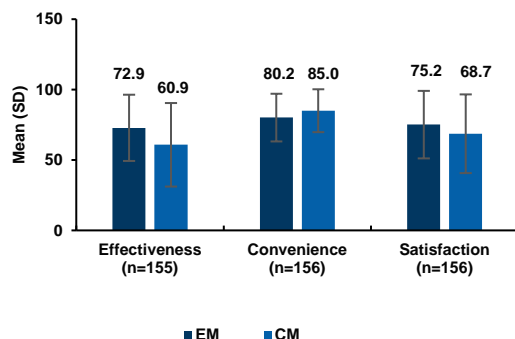


## Satisfaction with erenumab: TSQM-9

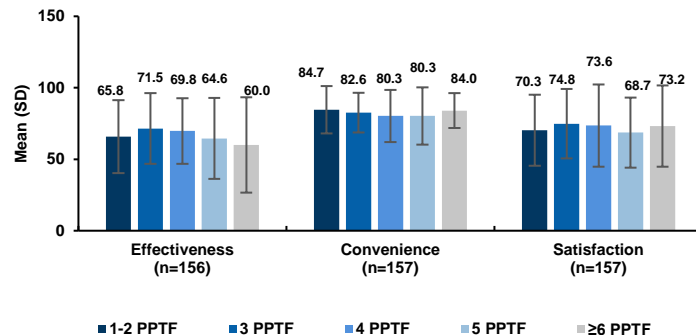
Month 6: TSQM-9 by gender



Month 6: TSQM-9 by migraine type



Month 6: TSQM-9 by PPTF group



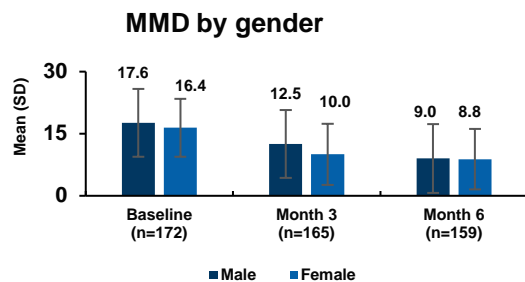
- No statistical difference between genders was observed in TSQM-9 scores for effectiveness (MWU  $p=0.187$ ), convenience (MWU  $p=0.112$ ) or global satisfaction (MWU  $p=0.080$ )
- There was a significant difference between EM and CM groups in TSQM-9 scores for effectiveness (MWU  $p=0.011$ ) but not for convenience (MWU  $p=0.065$ ) or global satisfaction (MWU  $p=0.153$ )
- PPTF had no significant impact on TSQM-9 scores for effectiveness (KS  $p=0.657$ ), convenience (KS  $p=0.858$ ) or global satisfaction (KS  $p=0.713$ )



## Results

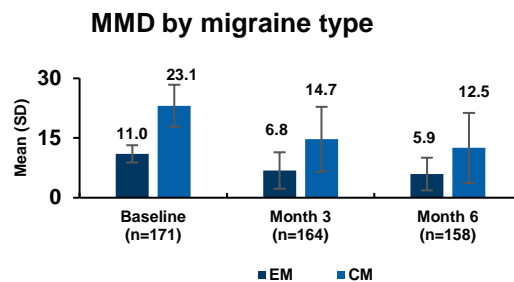


## Effect of erenumab on MMDs



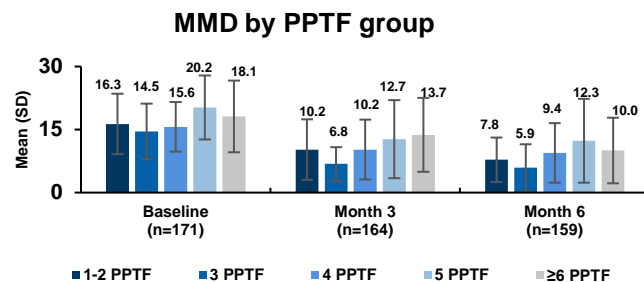
Change from baseline, mean (SD)

Visit	Male	Female
Month 3	-5.1 (6.4)	-6.3 (6.2)
Month 6	-8.4 (8.7)	-7.4 (6.6)



Change from baseline, mean (SD)

Visit	EM	CM
Month 3	-4.2 (4.9)	-8.3 (6.9)
Month 6	-5.1 (4.4)	-10.7 (8.2)



Change from baseline, mean (SD)

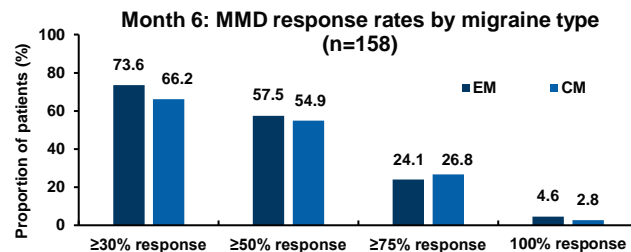
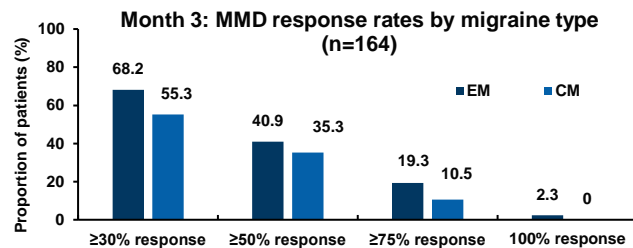
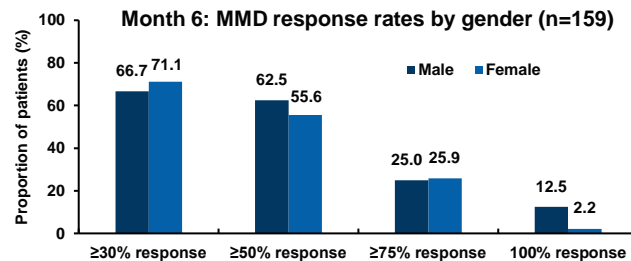
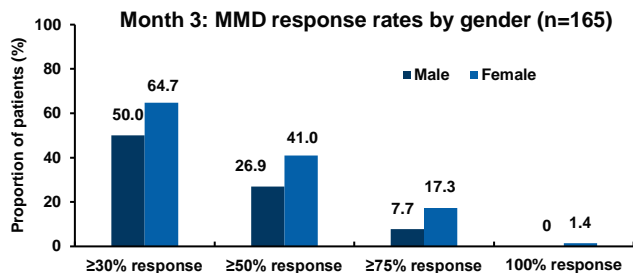
Visit	1-2 PPTF	3 PPTF	4 PPTF	5 PPTF	≥6 PPTF
Month 3	-6.0 (6.6)	-7.3 (5.5)	-5.4 (6.4)	-7.6 (7.1)	-4.4 (5.3)
Month 6	-8.3 (8.4)	-7.9 (5.1)	-6.2 (6.8)	-7.9 (7.6)	-8.0 (7.2)

- Erenumab significantly reduced MMDs from baseline to Month 3 and Month 6 (WSR both  $p < 0.001$ ) in both the genders and patients with either EM or CM
- Erenumab significantly reduced MMDs in all PPTF groups from baseline to Month 3 (KS  $p = 0.013$ ) and Month 6 (KS  $p = 0.014$ )

## Results



## Effect of erenumab on MMDs: response rates

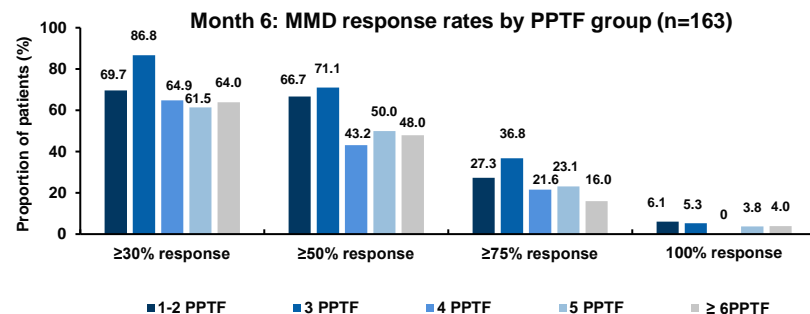
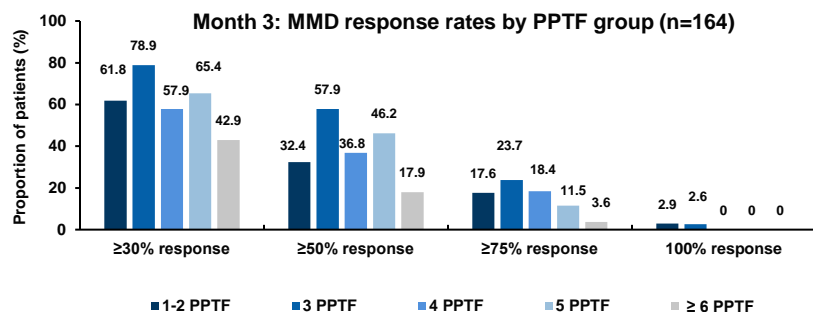


- MMD response rates were not significantly different between genders except 100% response rate for Month 6 (CS p=0.015)
- MMD response rates were not significantly different between migraine types

## Results



## Effect of erenumab on MMDs: response rates



- MMD response rates were not significantly different between PPTF groups except 50% response rate by PPTF for Month 3 (CS  $p=0.016$ )

## Effect of erenumab on AMSM days

Visit	Mean (SD)
Baseline*	11.4 (7.5)
Month 3	7.2 (6.3)
Month 6	6.6 (5.4)

\* Average of 3 months prior to initiation of erenumab

AMSM, acute migraine-specific medication; CS, chi-square test; EM, episodic migraine; MMD, monthly migraine day; PPTF, prior prophylactic treatment failure; SD, standard deviation; WSR, Wilcoxon signed rank test.

- Erenumab significantly reduced the mean AMSM days (triptans and/or ergot derivatives) from baseline to Month 3 and Month 6 (WSR both  $p<0.001$ )

## Conclusions



- This was the first study that prospectively collected real-world data on erenumab under routine medical care in Switzerland
- In both the genders with either EM or CM and in patients with different PPTFs, erenumab significantly
  - ✓ **reduced HIT-6 scores**, indicating improvement in quality of life
  - ✓ **reduced mMIDAS scores**, indicating improvement in migraine-related disability
  - ✓ **reduced IMPAC scores**, indicating decreased impact on spouses and children of patients
  - ✓ **reduced MMDs**, which was also reflected in response rates
  - ✓ **reduced AMSM days**, indicating lower need for acute migraine therapy
- Patients reported consistent treatment satisfaction with erenumab across gender, migraine type and PPTF group
- The SQUARE study provides insights into the effectiveness of erenumab in a real-world scenario

(MLR ID: 150385)