The SQUARE Study Design: A Multi-Centric, Non-Interventional Study to Evaluate the Impact of Erenumab on Quality of Life in a Real-World Population With Migraine

INTRODUCTION

• Erenumab (AMG334; Aimovig®) is a fully human monoclonal antibody specifically designed for the preventive treatment of migraine and has been used by over 250,000 patients since it was first made available.
• In pivotal trials, erenumab showed significant improvements in the frequency and burden of episodic and chronic migraine[1]. However, real-world evidence to complement these findings in a setting of routine medical care is lacking.

OBJECTIVE

• To present the study design of the non-interventional SQUARE study (Swiss Quality of life and healthcare Impact Assessment in a Real-world Erenumab treated migraine population, CAM033ACH01) which aims to collect important real-world clinical data on the impact of erenumab on patient-reported quality of life, as well as treatment satisfaction and persistence in a real-world migraine population.

METHODS

Study Design

• SQUARE is a non-interventional study to observe the use of erenumab, in a post-launching setting of 20 migraine clinics in Switzerland (Figure 1).

Figure 1. Study Design

• Both migraine care specialist centers and general neurologists in all geographical regions of Switzerland were included in the study in order to obtain a representative sample of the whole migraine treatment landscape (Figure 2).

Figure 2. Participating study sites

• Data collection will be facilitated by offering automatic data transfer from the 'Migraine Buddy' mobile application (Figure 3).
• The data of this study will be pooled with data from similar non-interventional studies of other European countries (umbrella protocol with aligned endpoints) and schedules.

Inclusion criteria

• Adults with a diagnosis of migraine according to the International Classification of Headache Disorders (ICHD-3[4]).
• Written informed consent will be obtained from patients before participating in the study.
• Decision that the patient will be initiated on erenumab in alignment with the Swiss label to be taken prior to enrollment
• Patient is willing and able to complete migraine diary during course of the study, and to complete PRO questionnaires.

Exclusion criteria

• Use of investigational drugs during the study.
• OR within 3 months before enrollment
• OR within 5 half-lives of investigational drug before enrollment
• OR until the expected pharmacodynamic effect has returned to baseline, whichever is longer
• Prior treatment with erenumab or any CGRP (receptor)-based therapy

Figure 3. Use of ‘Migraine Buddy’ mobile application as an easy way to track migraine in a non-interventional study

Sample size

• For within-group changes of HT-6, a minimum important difference of −3.7 has been reported in the literature[2]. Based on the observed variability of HT-6 in the BECOME[3] and STRIVE[5] studies, it has been calculated that a sample size of 77 patients with migraine is required for statistical analysis. Considering an expected drop-out rate of 60%, a total sample size of 150 patients will be recruited from 20 sites across all geographical regions of Switzerland.

Primary endpoint

• Change of Headache Impact Test (HT-6) scores after 6 months post initiation compared to baseline

Secondary endpoints

• Change of HT-6, modified migraine disability assessment test (mMIDAS with a 1-month recall period) and Impact of Migraine on Partners and Adolescent Children (IMPAC) scores after 3, 12, 15, and 24 months compared to baseline
• Total scores on TSQM-9 after 6 months
• Physician convenience/practically after 3, 6, 12, 15, 18 and 24 months
• Percentage of patients without permanent discontinuation of erenumab for any reason after 3, 6, 12, 15, 18 and 24 months
• Number of treatment days and total drug exposure within 24-months follow up
• Percentage of patients escalated and de-escalated between 70 mg and 140 mg of erenumab and the reason for the same
• Change in number of hospitalizations, ER visits and physician visits after 3, 6, 12, 15, 18 and 24 months compared to baseline
• Change in monthly migraine days and the achievement of at least 50% and 75% and 100% reduction after 3, 6, 12, 15, 18 and 24 months compared to baseline
• Change in menstrually-related migraine days, monthly acute medication treatment days after 3, 6, 12, 15, 18, and 24 months compared to baseline

Conclusions

• This study is among the first designed studies to describe the impact of erenumab in a real-world setting
• The data of this study will be pooled with data from similar non-interventional studies of other European countries, allowing post-hoc data pooling and cross-comparison
• A digital solution using the ‘Migraine Buddy’ mobile application has been implemented to gain higher-resolution migraine data while facilitating data entry and posing no additional burden on study sites
• Results from this endeavor will corroborate the body of evidence available for erenumab in medical practice
• The study is currently recruiting patients and primary results will be available in 2021

METHODS (Continued)

Statistical methods

• Primarily descriptive statistics will be used to evaluate the results
• All patients who receive at least one dose of erenumab and for whom subsequent documentation after baseline will be available will be included in the evaluation

Limitations

• In Switzerland, Aimovig is reimbursed for migraine patients with 8 or more migraine days per month, with an episode duration of at least 4 hours and a documented diary over at least 3 months prior to treatment initiation. Aimovig treatment has to be discontinued if no reduction in migraine days is seen at 3 months after initiation, or if the 10% rule is met within 6 months after initiation.
• The primary endpoint was hence chosen for month 6 and the sample size adjusted to account for early drop-outs

REFERENCES


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DISCLOSURES

• This study was sponsored by Novartis Pharma Switzerland AG, Rotkreuz, Switzerland. Erenumab is co-developed by Novartis and Amgen.
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