OPR-136

# Consistent efficacy and safety of erenumab in episodic migraine patients during a 5-year, open-label extension study

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# Disclosures

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# Aim and Methods

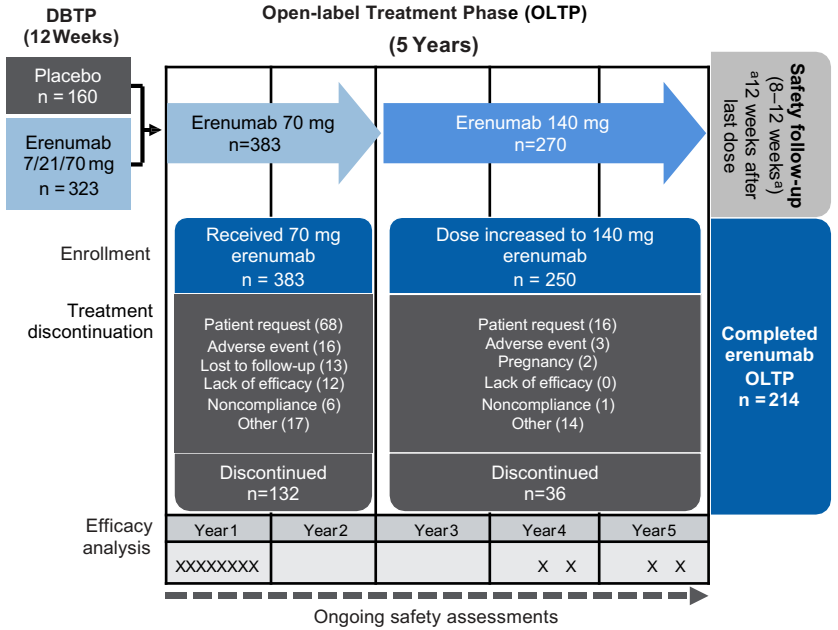
## Objective

- To evaluate the long-term efficacy and safety of erenumab in patients with episodic migraine who completed a 5-year treatment (Clinicaltrials.gov NCT01952574)

## Methods

- Patients included in the completer analysis set if they had received the last scheduled erenumab 140 mg at week 264
- Baseline defined as 4-week period prior to the double-blind treatment phase (DBTP)
- DBTP safety assessed using data pooled from 4 pivotal studies in episodic and chronic migraine (12 weeks)[1]

## Study design and disposition




1. Ashina et al, Cephalalgia, 2019;39(14):1798-1808

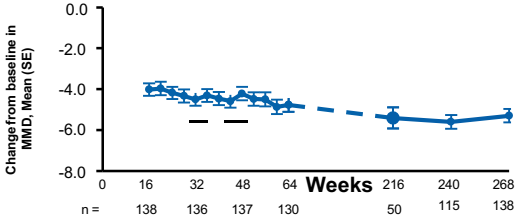
# Results

| Baseline characteristics | All patients (n = 383) | Completers (n = 214) |
|---|---|---|
| **Demographics** | | |
| Age, years | 41.3 (10.9) | 42.3 (10.8) |
| Sex, female, n (%) | 303 (79.1) | 171 (79.9) |
| Race, white, n (%) | 354 (92.4) | 201 (93.9) |
| **Baseline disease characteristics** | | |
| Age at migraine onset, years | 20.9 (11.3) | 21.8 (12.0) |
| Duration of disease, years | 20.9 (11.9) | 21.1 (11.7) |
| History of migraine with aura, n (%) | 137 (35.8) | 81 (37.9) |
| Monthly migraine days | 8.7 (2.7) | 8.6 (2.7) |
| Monthly acute migraine-specific medication days[a] | 4.3 (3.7) | 4.5 (3.6) |
| **Prior preventive therapy, n (%)** | | |
| Prior use | 169 (44.1) | 94 (43.9) |
| ≥1 Treatment failure[b] | 138 (36.0) | 76 (35.5) |

[a]Migraine-specific medications were triptans andergotamine derivatives.
[b]Included discontinuation due to lack of efficacy and/or side effects.
Data represent mean (SD) unless otherwise indicated.

**Erenumab** demonstrated **consistent and sustained** clinical responses in patients who completed **5 years** of treatment

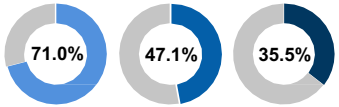
**Change in monthly migraine days**




Baseline monthly migraine days: **8.5 (0.2) days**

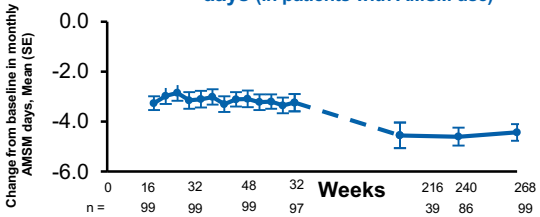
Mean (SE) change from baseline to year 5: **–5.3 (0.3) days**

**Monthly migraine day response rate at year 5**




≥ 50% response | ≥ 75% response | 100% response

**Change in acute migraine-specific medication days (in patients with AMSM use)**




Baseline monthly AMSM days: **6.2 (0.3) days**

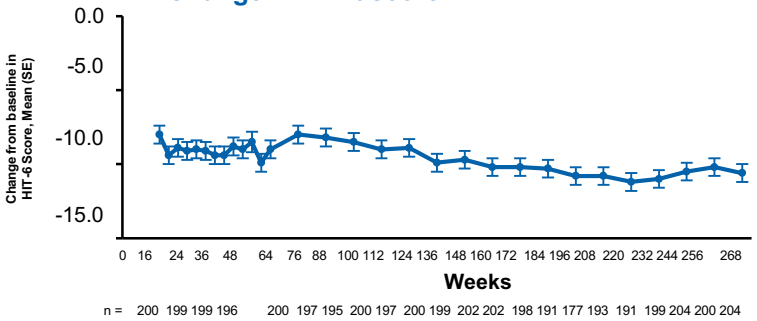
Mean (SE) change from baseline to year 5: **–4.4 (0.3) days**

AMSM, acute migraine-specific medication; MMD, monthly migraine day.

# Results

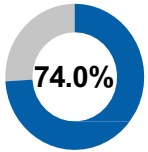
**Erenumab** demonstrated **consistent and sustained** clinically meaningful **improvements** in **patient reported outcomes** and increased **consecutive days free** of moderate/severe **headache** in patients who completed **5 years** of treatment

## Change in HIT-6 score



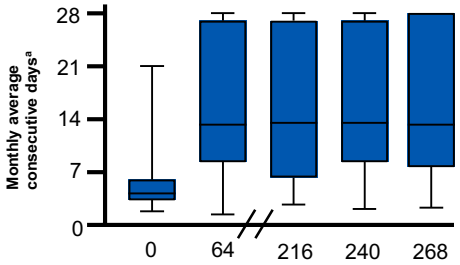

Baseline HIT-6 total score:
**59.9 (0.4) days**

Mean (SE) change from baseline to year 5:
**–10.6 (0.6) days**

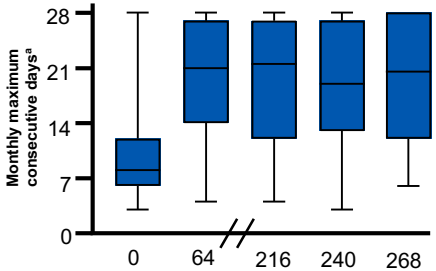


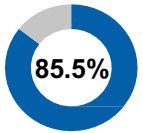

Proportion of patients achieving ≥5 point reduction

## Average consecutive days free of moderate/severe headache per month




## Maximum consecutive days free of moderate/severe headache per month




Proportion of patients with ≥1 interval of ≥14 consecutive days free of moderate/severe headache at week 216, 240, 264, or 268

[a]Maximum 28 days possible during 4-week evaluation period

# Results

## Exposure-adjusted adverse events
n [r]

| | Pooled DBTP[1] | | OLTP | Pooled DBTP | | OLTP |
|---|---|---|---|---|---|---|
| | Placebo (N=1043) | Erenumab 70/140 mg (N=1400) | Erenumab 70/140 mg (N=214) | Placebo (N=1043) | Erenumab 70/140 mg (N=1400) | Erenumab 70/140 mg (N=214) |
| All AEs | 280.2 / 100 PY (n=551) | 249.0 / 100 PY (n=727) | 108.6 / 100 PY (n=203) | | | |
| Grade ≥ 2 | 126.5 / 100 PY (n=321) | 105.4 / 100 PY (n=405) | 54.0 / 100 PY (n=186) | | | |
| Grade ≥ 3 | 12.8 / 100 PY (n=40) | 12.4 / 100 PY (n=58) | 6.2 / 100 PY (n=57) | | | |
| SAEs | | | | 6.3 / 100 PY (n=20) | 5.9 / 100 PY (n=28) | 3.1 / 100 PY (n=31) |
| Fatal SAEs | | | | 0.0 / 100 PY (n=0) | 0.0 / 100 PY (n=0) | <0.1 / 100 PY (n=1)[a] |

**Most frequent AEs (OLTP):**

- Nasopharyngitis (n=80 [9.7/100 PY])
- upper respiratory tract infection (n=59 [6.5/100 PY])
- influenza (n=48 [5.0/100 PY])

**SAEs reported by >1 patient each (OLTP):**

Osteoarthritis (n=2), uterine leiomyoma (n=2), ligament rupture (n=2), appendicitis (n=2)

**There was no increased emergence of adverse events over time in patients who completed 5 years of treatment**

[a]One fatality ("death unattended") occurred during the safety follow-up when no erenumab was administered; considered unrelated to study drug by the investigator.
PY, patient year

1. Ashina et al, Cephalalgia, 2019;39(14):1798-1808

# Conclusions

- Erenumab demonstrated consistent and sustained clinical responses in patients who completed 5 years of treatment
  - Maintained reductions in monthly migraine days and AMSM days
  - Maintained clinically meaningful improvements in HIT-6
  - Majority of patients achieved ≥50% reduction in monthly migraine days from baseline
  - Increased average and maximum monthly headache-free intervals
- Demographics and baseline characteristics were similar between completers and the full study population
- No new safety signals were detected in patients who completed the 5-year extended erenumab treatment period
  - Exposure-adjusted AEs and SAEs during OLTP were lower than that observed for placebo during DBTP

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