Oral abstract presentation number

Erenumab versus topiramate for the prevention of migraine: Results of a post-hoc efficacy analysis

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AMGEN NOVARTIS

Disclosures

Uwe Reuter — received honoraria for consulting and lectures within the past 3 years from Abbvie, Amgen, PharmAllergan, Eli Lilly, Lundbeck, Novartis Pharma, Hormosan Pharma, electroCore, Medscape, Novartis, Pfizer, StreaMedUp, Teva; UR holds no stocks of pharmaceutical companies or medical device companies

Marc Ehrlich, Monika Maier-Peuschel, Christian Sieder and Christian Hentschke are employees at Novartis**.**

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Background

The HER-MES trial is the first and only head-to-head randomized, controlled study comparing a CGRP pathway treatment (erenumab) with a standard of care therapy (topiramate) for migraine prevention

The HER-MES study demonstrated a **significantly superior tolerability and effectiveness** of erenumab compared with topiramate[1]

HER-MES was designed to compare treatment effectiveness (a combination of tolerability and efficacy), taking into account the potential impact of a treatment's tolerability on its efficacy in migraine prevention

Treatment efficacy amongst adherent patients is an additional important factor when it comes to treatment decision-making in migraine prevention. Thus, we will address the following question through a post-hoc analysis:

Does erenumab show better efficacy than topiramate amongst those patients who completed the HER-MES trial on study drug?

1) Reuter et. al., Erenumab versus topiramate for the prevention of migraine: Results of a randomized active-controlled double-dummy trial (HER-MES); Poster P223LB presented at the 63rd American Headache Society (AHS) Congress

Methods

Post-hoc sensitivity analysis

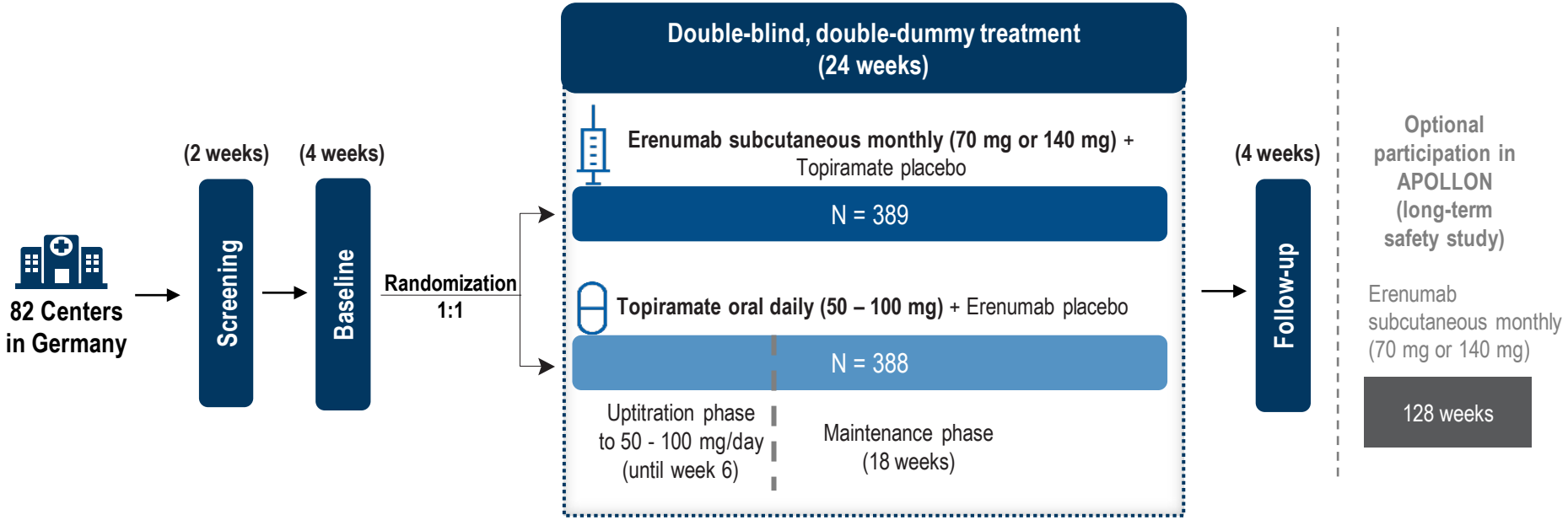
The presented post-hoc sensitivity analysis displays a hypothetical scenario in which all patients had tolerated their randomized treatment (erenumab/topiramate)

Efficacy values of patients who discontinued the study treatment were handled by using multiple imputation based on the observed on-treatment values in this trial.

This intention to treat analysis was performed in the population of the full analysis set (FAS) and preserves the randomization of the clinical trial.

Methods

Study design

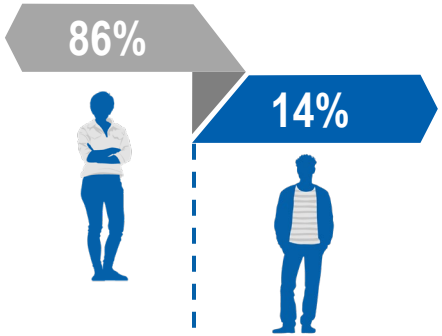


Stratification factor: monthly migraine day frequency

Results

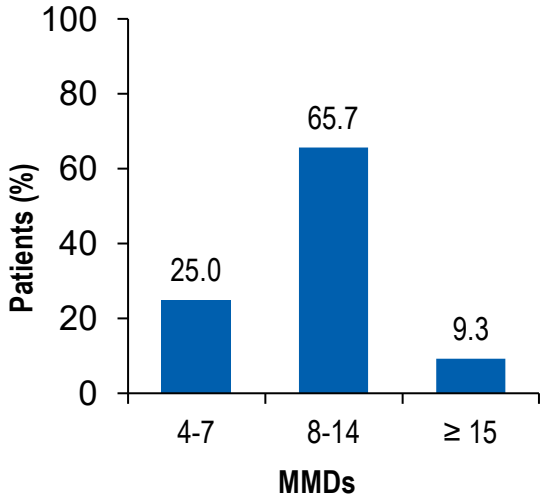
Patient characteristics at baseline

777 Patients were randomized

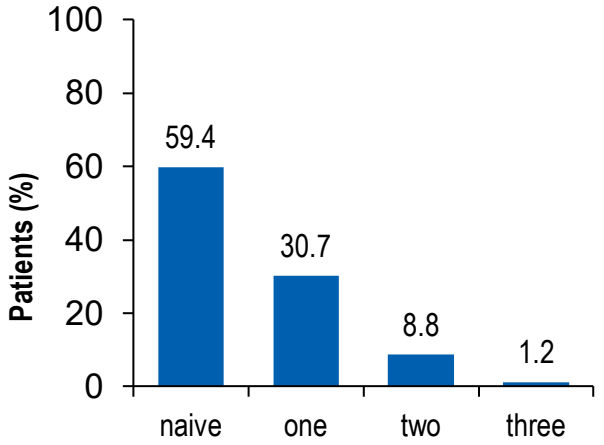


- Ø 41 years old
- Ø 22 years since disease onset
- Ø 10.4 MMDs

Stratification



Prior prophylactic treatment failure*



*Out of metoprolol/ propranolol, amitriptyline, flunarizine

MMDs = monthly migraine days

Results

Proportion of patients who discontinued study medication during the 24-weeks double-blind treatment phase.

Category	Erenumab (N=389) n (%)	Topiramate (N=388) n (%)
Patients who completed double blind treatment (%)	334 (85.9)	231 (59.5)
Patients who discontinued double blind treatment (%)	55 (14.1)	157 (40.5)
Reason for discontinuation		
Adverse Events	41 (10.6)	151 (38.9)
Lack of efficacy	1 (0.3)	-
Lost to follow up	4 (1.0)	1 (0.3)
Withdrawal of informed consent	1 (0.3)	-
Patient/guardian decision	4 (1.0)	3 (0.8)
Physician decision	1 (0.3)	-
Protocol deviation	3* (0.8)	1 (0.3)
Pregnancy	-	1 (0.3)

*One patient did not receive erenumab.

Results

Proportion of patients who discontinued study medication during the 24-weeks double-blind treatment phase.

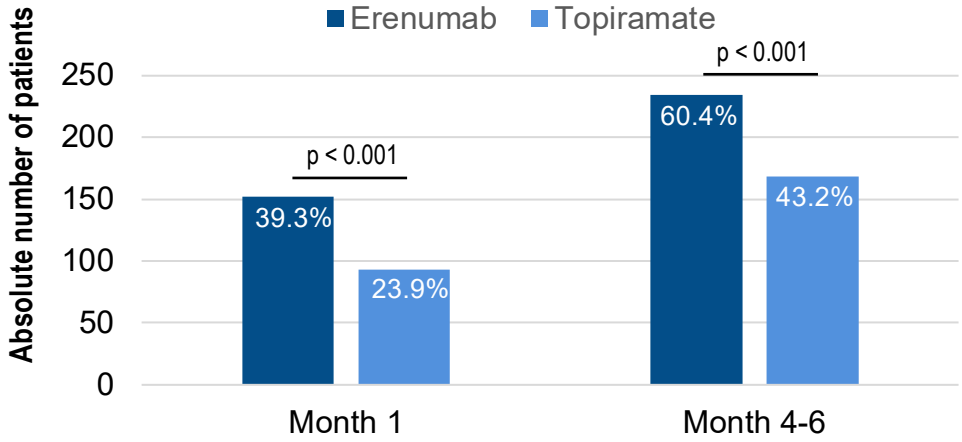
Category	Erenumab (N=389) n (%)	Topiramate (N=388) n (%)
Patients who completed double blind treatment (%)	334 (85.9)	231 (59.5)
Patients who discontinued double blind treatment (%)	55 (14.1)	157 (40.5)

- **The hereafter presented sensitivity analysis displays a hypothetical scenario to evaluate the efficacy of erenumab vs. topiramate as if all patients had tolerated their randomized treatment (erenumab/topiramate)**
- **Missing values from patients who discontinued study treatment were added through a multiple imputation as responders based on the observed on-treatment values in this trial**

*One patient did

Results

Proportion of patients with at least a 50% reduction in MMD

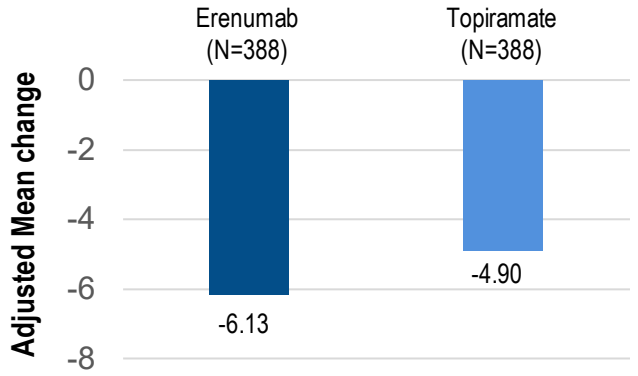


Odd's Ratio (OR)	2.06	2.02
95% CI	1.49 – 2.84	1.48 – 2.76

Patients were **2-fold (OR=2) more likely to have a ≥ 50%** with erenumab versus topiramate. This effect was observed starting from month 1 and confirmed in months 4-6.

Results

Change from baseline in MMD over last three months (month 4, 5, 6)



Difference vs topiramate: −1.24
95% CI: −1.87, −0.61; P<0.001

CI, confidence interval; MMD, monthly migraine days

Patients receiving **erenumab** reported a **significantly larger reduction of MMD** versus topiramate.

Conclusions

- The HER-MES post-hoc completer analysis confirmed the good efficacy of topiramate for migraine prevention but also demonstrated that **erenumab is an even more efficient therapy for migraine prophylaxis** in regards to:
  - **achieving a ≥50% reduction of MMD**
  - **the numeric reduction of MMD**
  - **early onset of action (significant superiority starting from month 1)**

- The post-hoc completer analysis of the HER-MES trial further supports the initially published[1] superior effectiveness results of erenumab compared with topiramate in the prevention of migraine across a broad patient population.

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