Final results of the SPECTRE study: real-world data giving an insight into the treatment of migraine patients with erenumab in Germany

Charly Gaul[1], Mirja Koch[2], Cordula Weiss[3]

[1] Headache Center, Frankfurt, Germany

[2] Novartis Pharma AG, Basel, Switzerland

[3] Novartis Pharma GmbH, Nuremberg, Germany

Poster number: 011, Neighborhood 12

Session name: P12: Headache: Towards Precision Medicine 2

Session time: Wednesday, April 26, 5:30 PM – 6:30 PM

Poster Presentation at the American Academy of Neurology (AAN) 2023, April 22-27, 2023

Disclosures

Dr. Charly Gaul received honoraria for consulting and lectures within the past three years from Allergan Pharma, Lilly, Novartis Pharma, Hormosan Pharma, Grünenthal, Sanofi-Aventis, Weber & Weber, Lundbeck, Perfood, and TEVA. His research is supported by a grant of the German Research Foundation (DFG). He does not hold any stocks of pharmaceutical companies. He is honorary secretary of the German Migraine and Headache Society.

Dr. Mirja Koch is an employee of Novartis AG.

Dr. Cordula Weiss is an employee of Novartis Pharma GmbH.

Funding

This study was supported by Novartis Pharma GmbH, Nuremberg, Germany.

Erenumab is co-developed by Novartis and Amgen.

Background, Objective and Methods

Background

- Migraine is among the most common neurological diseases world-wide.
- Erenumab is a fully human monoclonal antibody acting as calcitonin gene-related peptide (CGRP)-receptor antagonist[1].
- Erenumab demonstrated efficacy and safety in randomized controlled trials and was the first anti-CGRP pathway treatment approved for migraine prevention in adults[2-5].
- However, there is still a need to better understand treatment with erenumab in routine clinical practice by headache specialists outside these controlled settings.

Objective

The aim of the SPECTRE study was to better understand patient profiles and treatment patterns for erenumab in Germany based on migraine characteristics and comorbidities.

Methods & study design

- SPECTRE: observational, non-interventional, multi-center, open label, single-arm study of patients being treated with erenumab in Germany as per local label and local clinical practice (**Figure 1**).
- 105 sites in Germany had enrolled 571 adult migraine patients (with ≥ 4 monthly headache days) receiving erenumab of which 556 patients were included in the full analysis set.

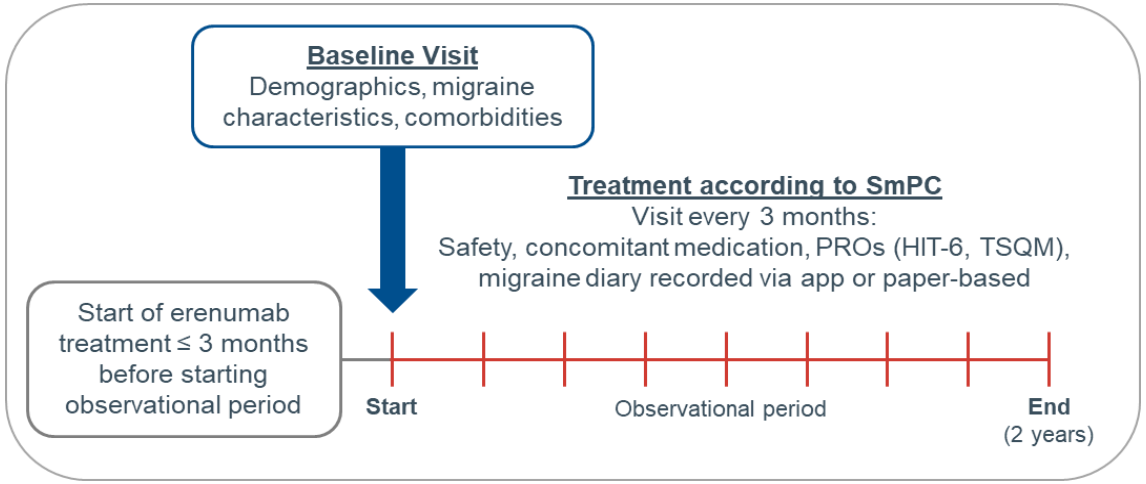

Figure 1: Study design.

SmPC, Summary of product characteristics; PRO, Patient Reported Outcome; HIT-6, Headache Impact Test-6; TSQM, Treatment Satisfaction Questionnaire for Medication.

1. Shi L, et al.: J Pharmacol Exp Ther. 2016; 356:223–231. 2. Sun H, et al.: Lancet Neurol. 2016; 15:382–390. 3. Dodick DW, et al.: Cephalalgia. 2018; 38:1026–1037. 4. Goadsby PJ, et al.: N Eng J Med. 2017; 377:2123–2132. 5. Reuter U, et al.: Lancet. 2018; 392:2280–2228. *Full analysis set= All patients who meet the selection criteria and with a documentation of the starting dose of erenumab

Patient Characteristics

C. Gaul, et al.

- 571 migraine patients at 105 sites in Germany
- 556 patients included in analysis

- The typical patient was female (89.0%), 45±12.3 years of age and diagnosed with chronic migraine (63.3%) and at least one comorbidity (75.9%) with the most common disorder being depression (27.2%) (**Table 1, Figure 2**).

Female, n (%)	495 (89.0)
Age (years), mean ± SD	45 ± 12.3
Non-smoker, n (%) (n=538)	458 (85.1)
Time since migraine diagnosis (years), mean ± SD	17.0 ± 13.2
Chronic migraine, n (%)	352 (63.3)
Treatment failures ≥ 4 , n (%) (n=542)	284 (52.4)
MHDs [a], mean ± SD (n=553)	14.6 ± 6.7
MMDs [a], mean ± SD	10.8 ± 5.4
Days per month without pain [a], mean ± SD (n=554)	15.5 ± 6.7
Days with acute medication [a], mean ± SD (n=554)	10.3 ± 5.5
Medication overuse, n (%)	151 (27.2)
At least one comorbidity, n (%)	422 (75.9)

Table 1: Patient characteristics (n = 556).

[a] During the last three months at baseline.
n, number of patients; SD, standard deviation; MHD, monthly headache days; MMD, monthly migraine days.

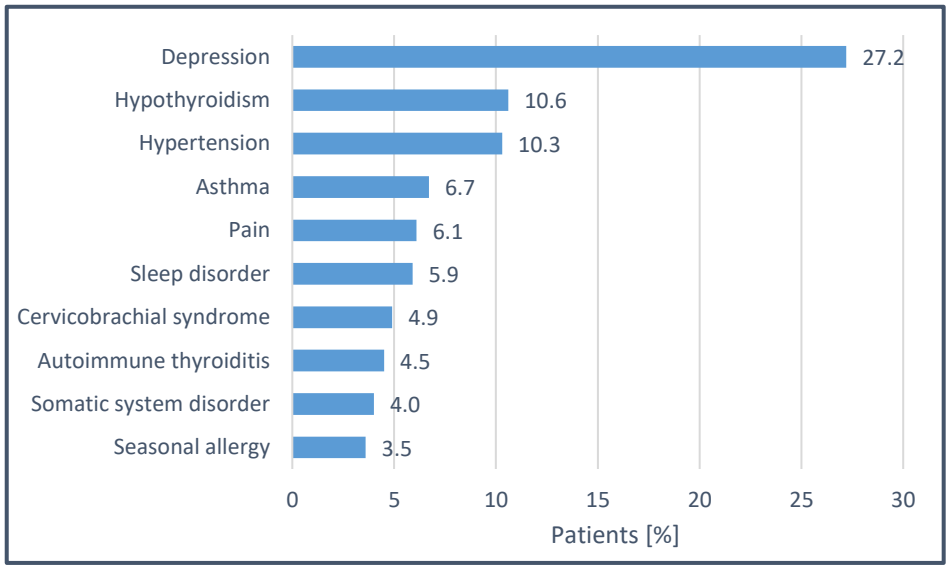

Figure 2: Most common comorbidities[b].

[b] Comorbidities documented at final analysis.

Starting Dose: depending on MHDs and time since diagnosis

C. Gaul, et al.

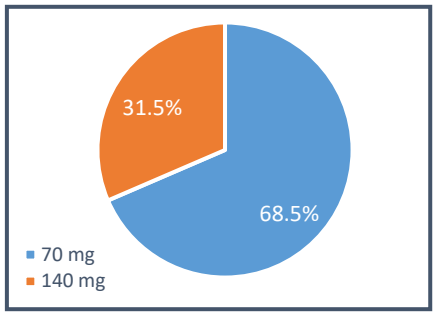

Figure 3: Starting dose.

- Majority of patients received 70 mg as starting dose from their treating physician (**Figure 3**)
- None of the recorded types of comorbidities (psychiatric, autoimmune, gastrointestinal and cardiac disorders) had an impact on the selection of the starting dose (**Figure 4**)
- Patients with a higher number of monthly headache days (MHDs) at baseline were more likely to receive a higher starting dose (**Figure 5**)
- Patients who were more recently diagnosed were more likely to receive a higher starting dose (**Figure 6**)

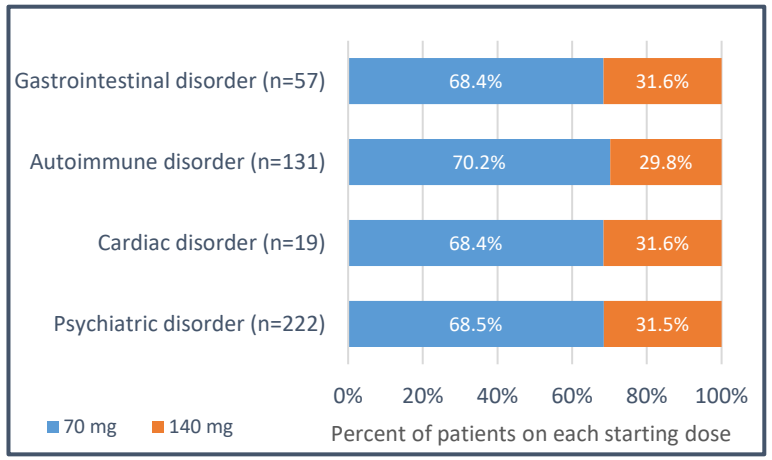

Figure 4: Starting dose in relation to type of comorbidity[a].
[a] Comorbidities documented at final analysis.

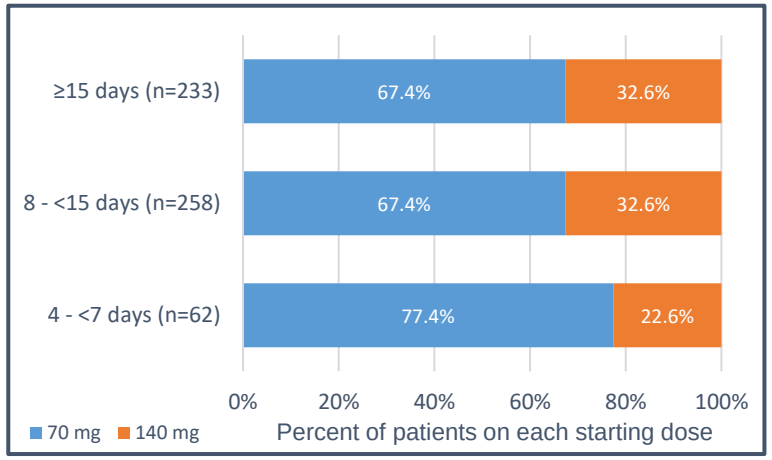

Figure 5: Starting dose in relation to MHDs.

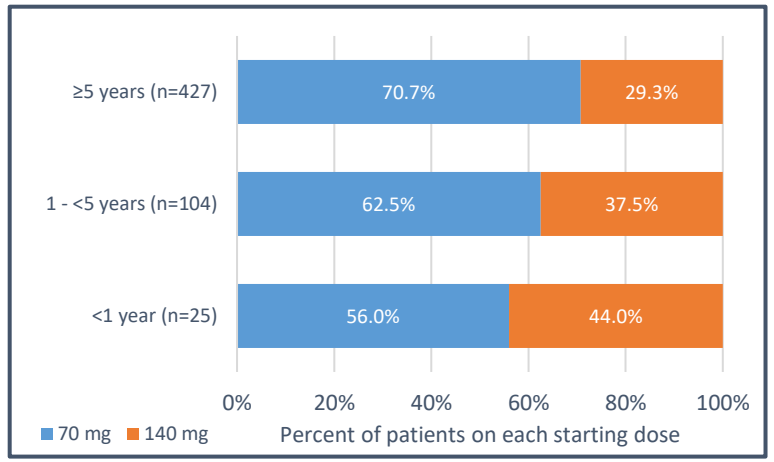

Figure 6: Starting dose in relation to time since diagnosis.

Reduction of MHDs and MMDs within 3 months of treatment

C. Gaul, et al.

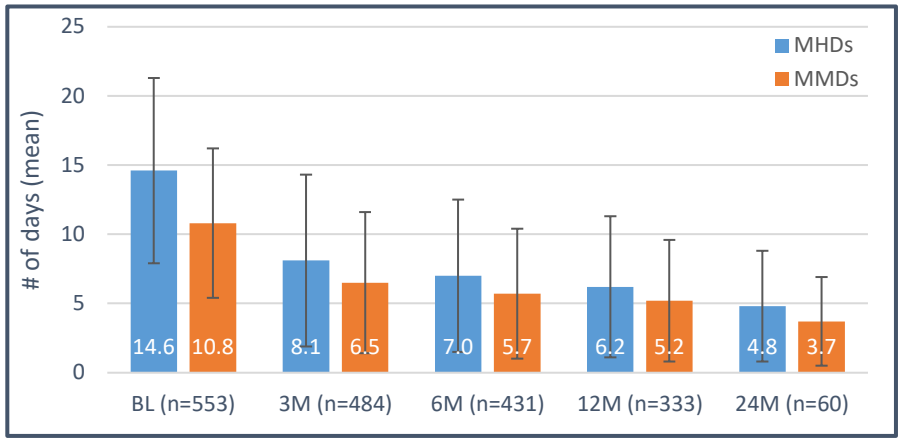

Figure 7: Monthly headache and migraine days (MHDs, MMDs) at baseline (BL)* and after 3, 6, 12 and 24 months.

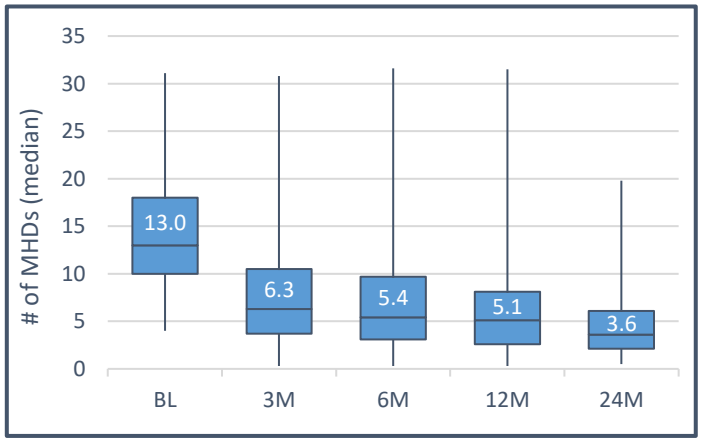

Figure 8: Monthly headache days (MHDs) at baseline (BL)* and after 3, 6, 12 and 24 months (median values).

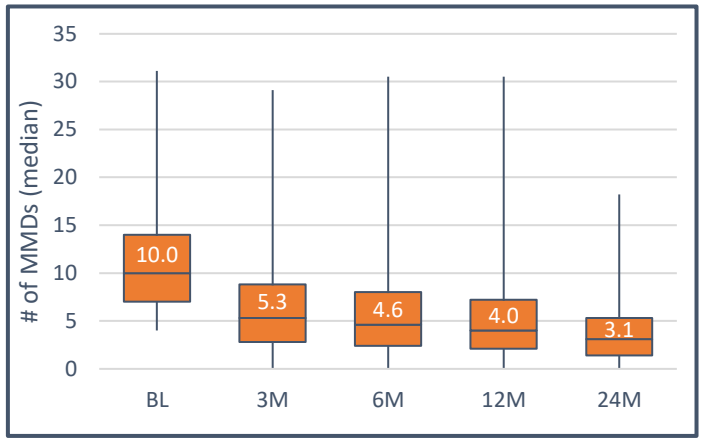

Figure 9: Monthly migraine days (MMDs) at baseline (BL)* and after 3, 6, 12 and 24 months (median values).

* MHDs and MMDs at baseline: average MHDs and MMDs in the last 3 months before study start.

- Within the first 3 months on treatment, average MHDs were reduced by more than 6 days (**Figure 7**).
- At baseline, all patients suffered from ≥4 MHDs (median: 13.0 MHDs) while the minimum value reported after 3 months on erenumab was 0.3 MHDs (median: 6.3 MHDs) (**Figure 8**). More than half of the patients showed ≥ 50% reduction in MHDs within the same timeframe (data not shown).
- The average number of MMDs decreased by more than 4 days during the first 3 months of treatment (**Figure 7**).
- Patients also reported ≥4 MMDs (median: 10.0 MMDs) which was reduced to a minimum of 0.0 MMDs within 3 months of treatment (**Figure 9**). After 6 months, 44.1% of patients reported <4 MMDs (data not shown).

Improved quality of life within 3 months of treatment

C. Gaul, et al.

- Patients' pain experience and quality of life improved within the first 3 months of treatment.
- At baseline, patients had an average of 15.5 pain-free days per month, after 3 months on erenumab, this increased by nearly 7 days to an average of 22.3 pain-free days per month (**Figure 10**).
- Patients also relied less on acute medication with the number of days with acute medication per month decreasing by about 50% from an average of 10.3 days at baseline to an average of 5.1 days within the first 3 months (**Figure 11**).
- HIT-6 scores improved by >6 points from 64.5 at baseline to 57.9 after 3 months (**Figure 12**), showing that the impact of headache on social functioning, role functioning, vitality, cognitive functioning and psychological distress decreased within the first 3 months on erenumab.
- Physicians reported therapy success as good or very good for about 75% of patients being treated with erenumab (data not shown).

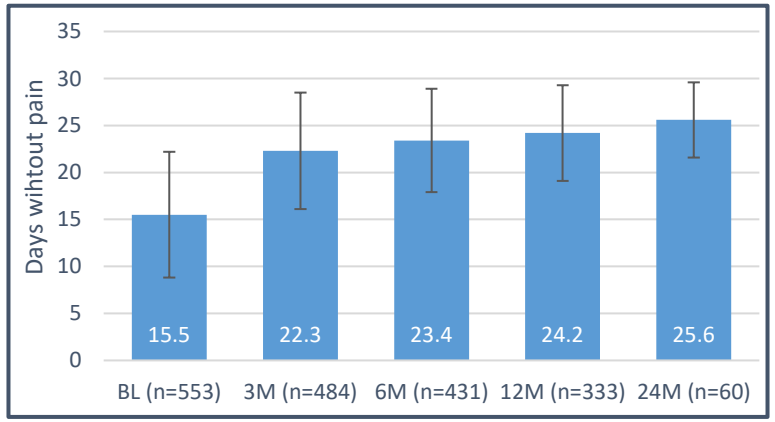

Figure 10: Days without pain per month at baseline (BL) and after 3, 6, 12 and 24 months.

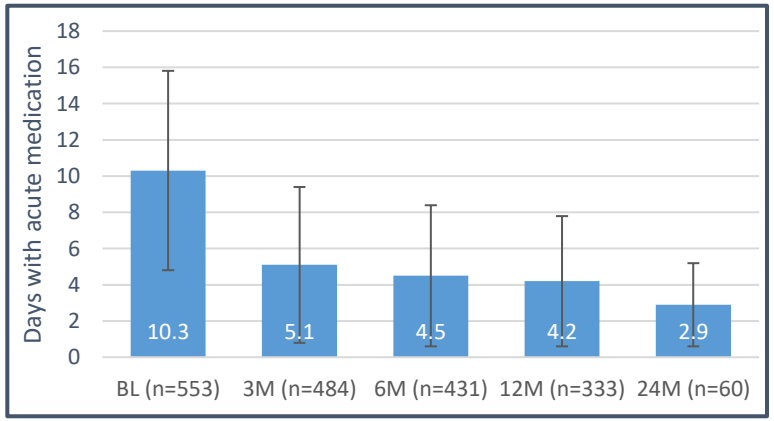

Figure 11: Days with acute medication per month at baseline (BL) and after 3, 6, 12 and 24 months.

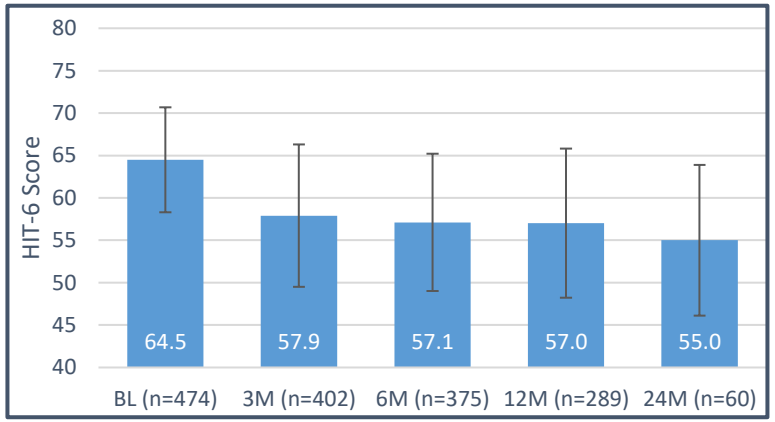

Figure 12: HIT-6 (Headache Impact Test) Scores at baseline (BL) and after 3, 6, 12 and 24 months (scale truncated for clarity).

Conclusions

The typical patient was female, about 45 years of age, diagnosed with chronic migraine and often suffering from a comorbidity, mainly depression.

The majority of patients received 70 mg as a starting dose. Patients with a higher number of MHDs and patients who had been diagnosed more recently were more likely to receive a higher starting dose (140 mg).

After 3 months of treatment with erenumab

- average MHDs were reduced by more than 6 days;
- average MMDs were reduced by about 5 days;
- pain-free days had improved by 7 days per month;
- Days with acute medication decreased by about 5 days per month;
- the HIT-6 score decreased by more than 6 points.

→ Patients' quality of life and pain experience improved within the first 3 months of treatment with erenumab.