FINAL RESULTS FROM A REAL-WORLD EVIDENCE STUDY ON THE TREATMENT OF MIGRAINE PATIENTS WITH ERENUMAB IN GERMANY (SPECTRE)

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Conflict of interest

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** and **Dr. Caroline Baufeld** are employees of Novartis Pharma.

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Introduction & 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 still exists 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 elucidate 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 in patients being treated with erenumab in Germany as per local label and local clinical practice (**Figure 1**)
- 139 sites in Germany with 572 adult migraine patients enrolled receiving erenumab treatment and of which 556 patients were included in the full analysis set*

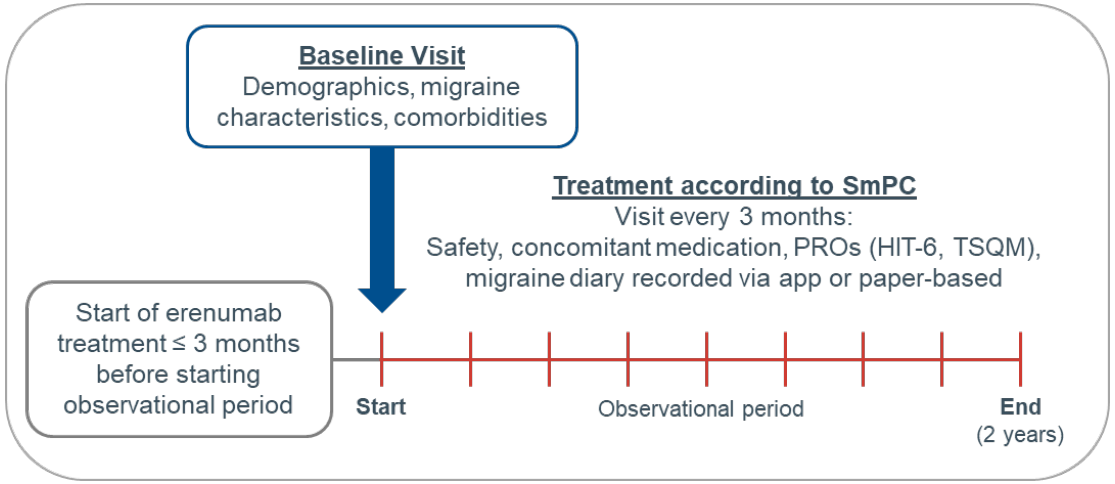

Figure 1: Study design. SmPC, Summary of product characteristics; PRO, Patient Reported Outcome; HIT-6, Headache Impact Test-6; TSQM, Treatment Satisfaction Questionnaire for Medication.

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

Results – Patient characteristics & comorbidities

Female, n (%)	495 (89)
Age (years), mean ± SD	45 ± 12.3
Time since migraine diagnosis (years), mean ± SD	18.9 ± 13.3
Chronic migraine, n (%)	352 (63.3)
MHDs [a], mean ± SD	14.6 ± 6.7
MMDs [a], mean ± SD	10.8 ± 5.4
Days with acute medication [a], mean ± SD	10.3 ± 5.5
Medication overuse, n (%)	151 (27.2)

Table 1: Patient characteristics (n = 572). [a] During the last three months at baseline. n, number of patients; SD, standard deviation; MHD, monthly headache days; MMD, monthly migraine days.

Type of prior prophylaxis	n	%	Time (months), mean ± SD
Topiramate	435	78.2	10.9 ± 17.8
Amitriptyline	385	69.2	11.2 ± 22.4
Metroprolol	282	50.7	12.4 ± 24.2
Flunarizine	280	50.4	6.0 ± 10.4
Onabotulinumtoxin A	161	29.0	10.8 ± 15.9
Valproate/ divalproex	88	15.8	9.5 ± 26.7
Propranolol	77	13.8	8.5 ± 14.7
Bisoprolol	61	11.0	14.9 ± 28.7
Candesartan	47	8.5	9.3 ± 14.6
Venlafaxine	31	5.6	12.0 ± 13.8

Table 2: Most commonly used prior prophylactics. Previous treatments are treatments that were discontinued before start with erenumab. Multiple entries possible. n, number of patients; SD, standard deviation.

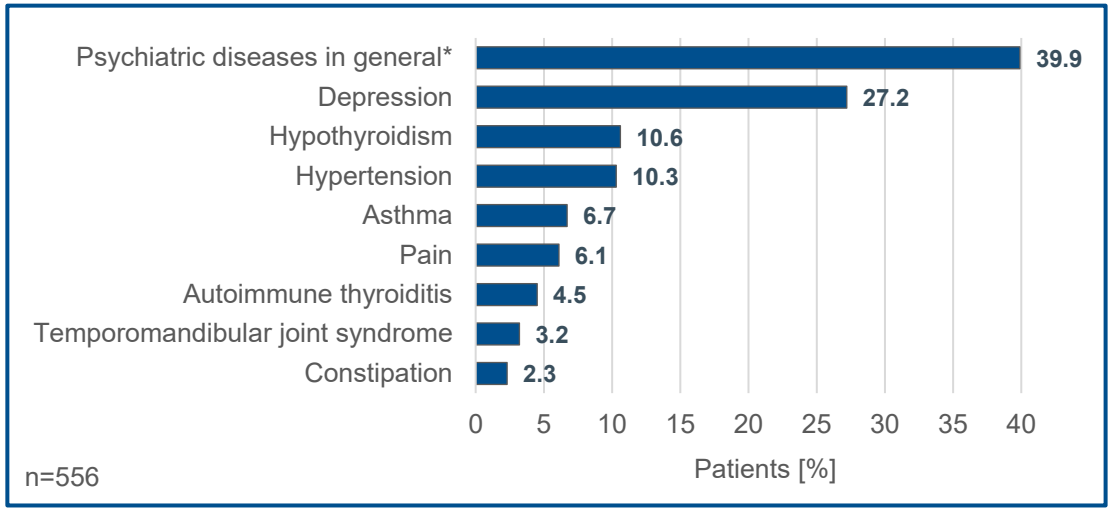

Figure 2: Most common comorbidities [b]. [b] Comorbidities documented at final analysis. * incl. depression

→ Final analysis of **556 patients treated for 2 years with erenumab**.

- The majority of erenumab patients were women with chronic migraine (**Table 1**), with a high proportion of psychiatric comorbidities (**Figure 2**).
- Nearly all migraine patients (98.2%) have received prophylactic treatment in the past. Topiramate and amitriptyline were used most, whereas bisoprolol and metroprolol were administered longest (**Table 2**).

Results – Erenumab dose & impact on MHDs

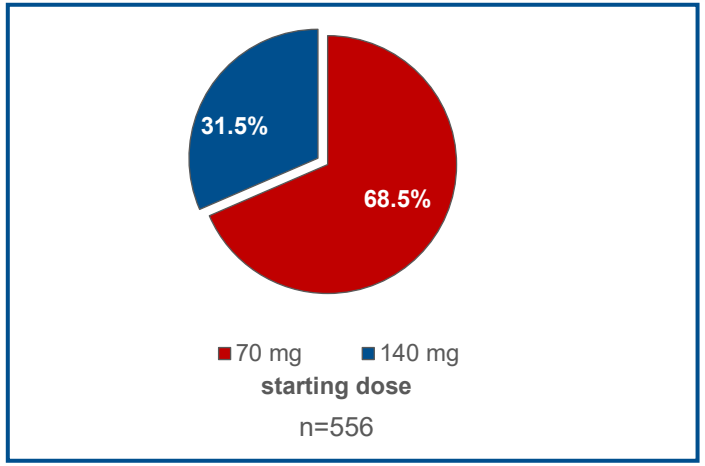

Figure 3: Starting dose.

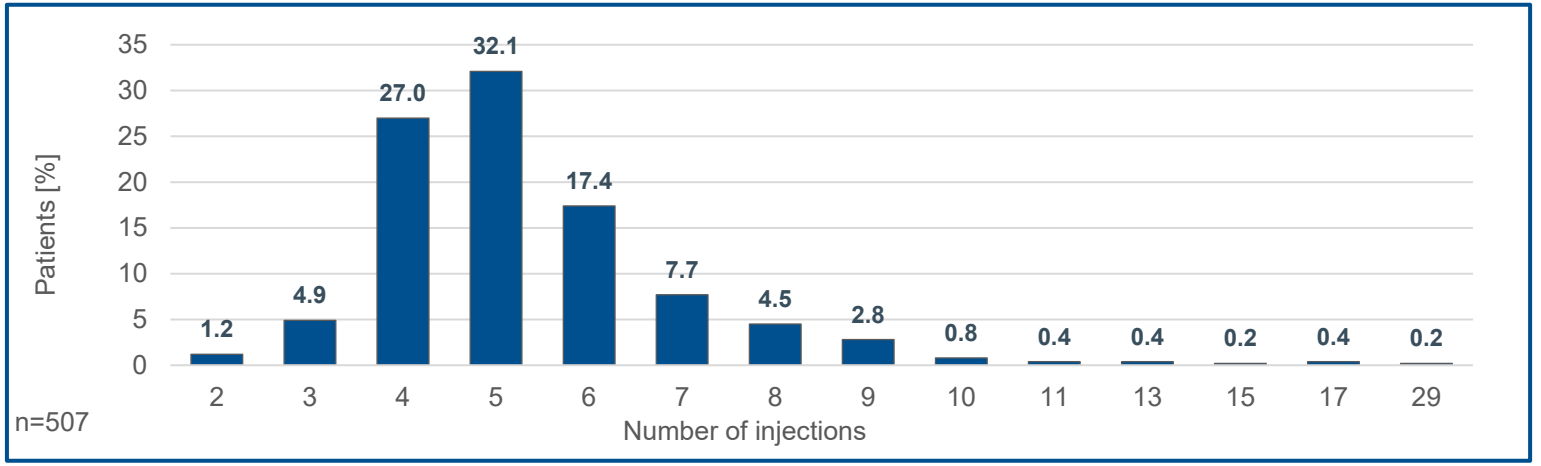

Figure 4: Number of injections in % patients who achieved ≥ 50% reduction in MHDs (monthly headache days)

- Most physicians used 70 mg as starting dose (**Figure 3**) which was increased after 5 (± 3.8) months in avg. (data not shown).
- Of the patients who started with 140 mg, 47.4% received the high dose because of the severity of their migraine (data not shown).
- 82,6% of patients required 6 or less injections of erenumab to reach a reduction of monthly headache days (MHDs) by at least 50% (**Figure 4**).
- Less than 2% of patients required more than 12 injections of erenumab to reach a 50% reduction of MHDs (**Figure 4**).

Results – Therapy response according to physicians and patients' diaries

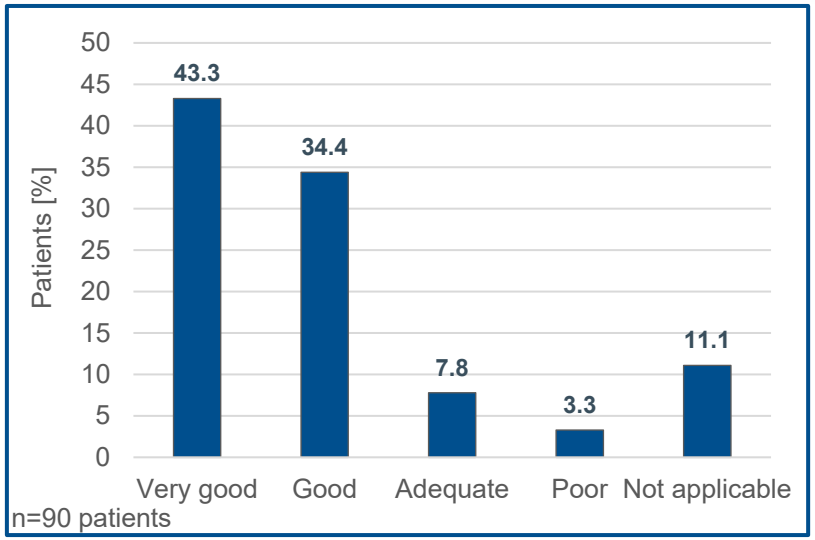

Figure 5: Therapy response according to physicians' judgement after two years of treatment with erenumab.

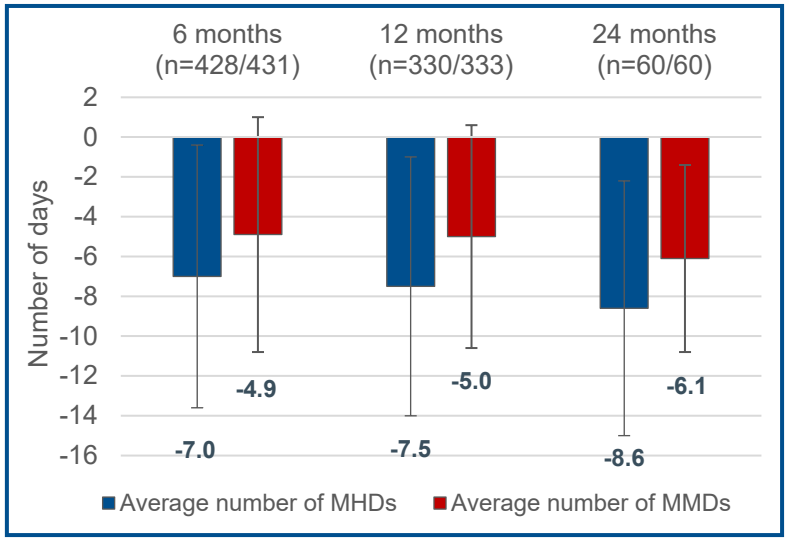

Figure 6: Changes in monthly headache (MHDs) and migraine days (MMDs) during two-year treatment with erenumab (mean ± SD).

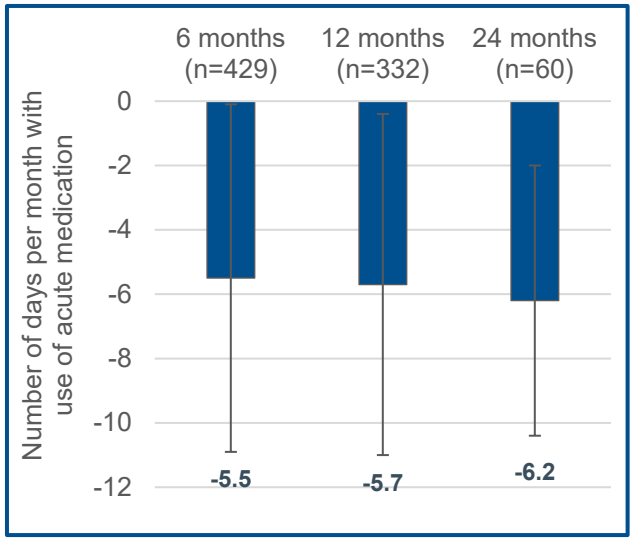

Figure 7: Changes in number of days per month with acute medication use during two-year treatment with erenumab (mean ± SD).

- For about three-fourths of patients being treated with erenumab, therapy success was judged by physicians as good or very good (**Figure 5**).
- After two years of erenumab treatment, monthly headache days were reduced by 8.6 days and monthly migraine days were reduced by 6.1 days compared to baseline (**Figure 6**).
- Use of acute medication by patients was reduced by 6.2 days per month during treatment with erenumab (**Figure 7**).

Results – Treatment response and satisfaction according to patient reported outcomes HIT-6 and TSQM

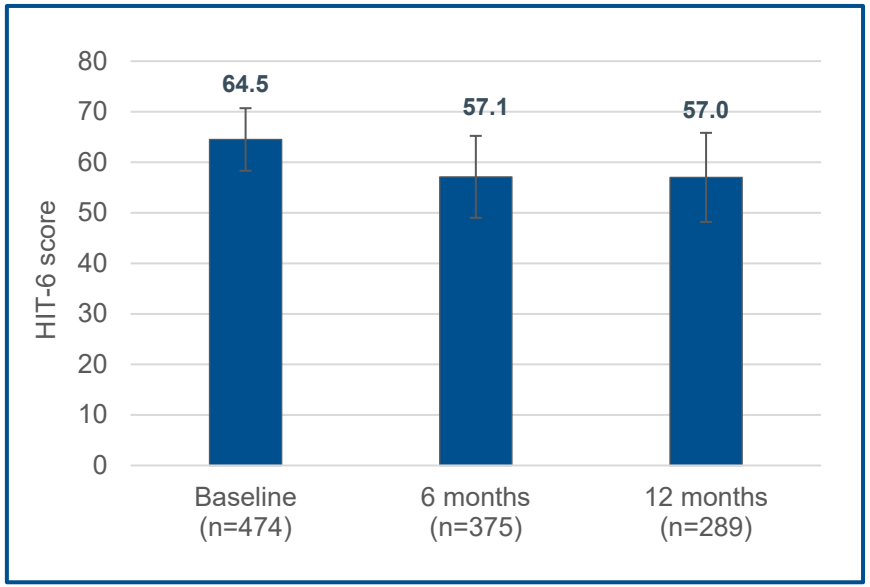

Figure 8: Treatment response according to HIT-6 score (mean ± SD).

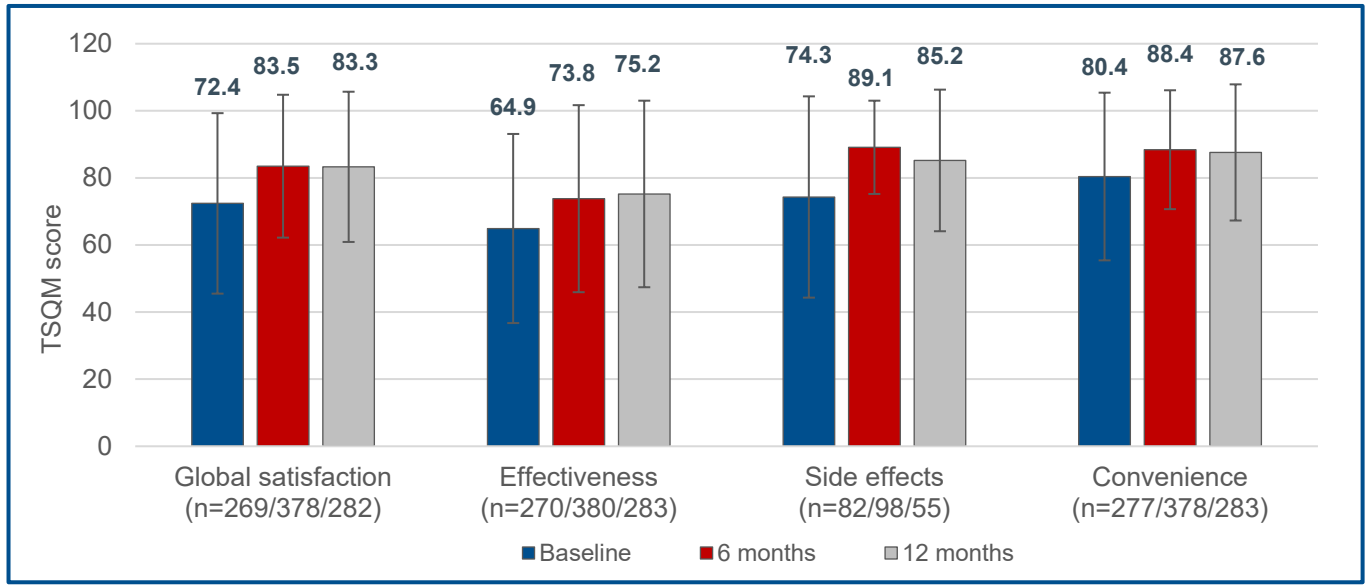

Figure 9: Treatment satisfaction according to TSQM score (mean ± SD).

- Over the course of one-year erenumab treatment, HIT-6 (Headache Impact Test-6) scores decreased from 64.5 to 57.0 (**Figure 8**).
- In general, treatment satisfaction as measured by TSQM (Treatment Satisfaction Questionnaire for Medication) was high and even increased during the first year of erenumab treatment (**Figure 9**).
- Patient satisfaction as assessed by TSQM peaked after six months of treatment with erenumab and remained sustained through 12 months of observation.

Conclusions

- The patient pool enrolled in SPECTRE has a long history of migraine, several prior treatment failures and a high representation of chronic patients and patients with a psychiatric comorbidity
- The majority of patients needed 6 or less injections to reach a 50% reduction of MHDs
- The HIT-6 score decreased in average after 3 months of treatment with erenumab by more than 7 points and remained at this level throughout the first year of erenumab treatment
- High treatment satisfaction scores were maintained throughout the 12 months observational period

- **The SPECTRE study provides valuable insights into (1) clinical practice of erenumab in Germany, (2) characterization of prescription patterns, and (3) analysis of the respective therapy response.**