



BASELINE DATA OF A REAL WORLD EVIDENCE STUDY CHARACTERIZING PRESCRIPTION PATTERNS IN EPISODIC AND CHRONIC MIGRAINE PATIENTS STARTING TREATMENT WITH ERENUMAB IN GERMANY (SPECTRE)

Gaul, C.¹, Koch, M.², Baufeld, C.²

¹Migraene and Headache Clinic Koenigstein/Germany

²Novartis Pharma GmbH, Nuremberg/Germany

Migraine Trust Virtual Symposium, 3–9 October, 2020

This study is supported by Novartis Pharma AG, Basel, Switzerland. Erenumab is co-developed by Amgen and Novartis.

**Background:**

Collection of information on monoclonal antibodies as a prophylactic treatment for migraine in the clinical routine of headache specialists outside randomised controlled trials is important. Erenumab, a monoclonal antibody targeting the Calcitonin Gene-Related Peptide (CGRP)–receptor, was approved with two monthly dosages: *70 mg and 140 mg*.

Methods:

- SPECTRE is an observational, non-interventional, multi-centre, open label, single-arm study in patients being treated with erenumab in Germany as per local label and local clinical practice.
- 1960 patients are planned to be enrolled from approximately 150 German centres.
- Patients either can be new on treatment with erenumab or have started treatment recently, but not more than 3 months before entering the study
- Patients who receive erenumab according to label will be observed for 24 months.
- No visit schedule will be imposed on participants to avoid interference with routine clinical care: one baseline evaluation and up to 8 visits may be documented within the observational period
- Apart from a headache diary, the patient-reported-outcome questionnaires HIT-6™ (*headache impact test*) and TSQM (*treatment satisfaction questionnaire of medication*) are used to assess the efficacy of erenumab and the satisfaction of the patients with the drug.



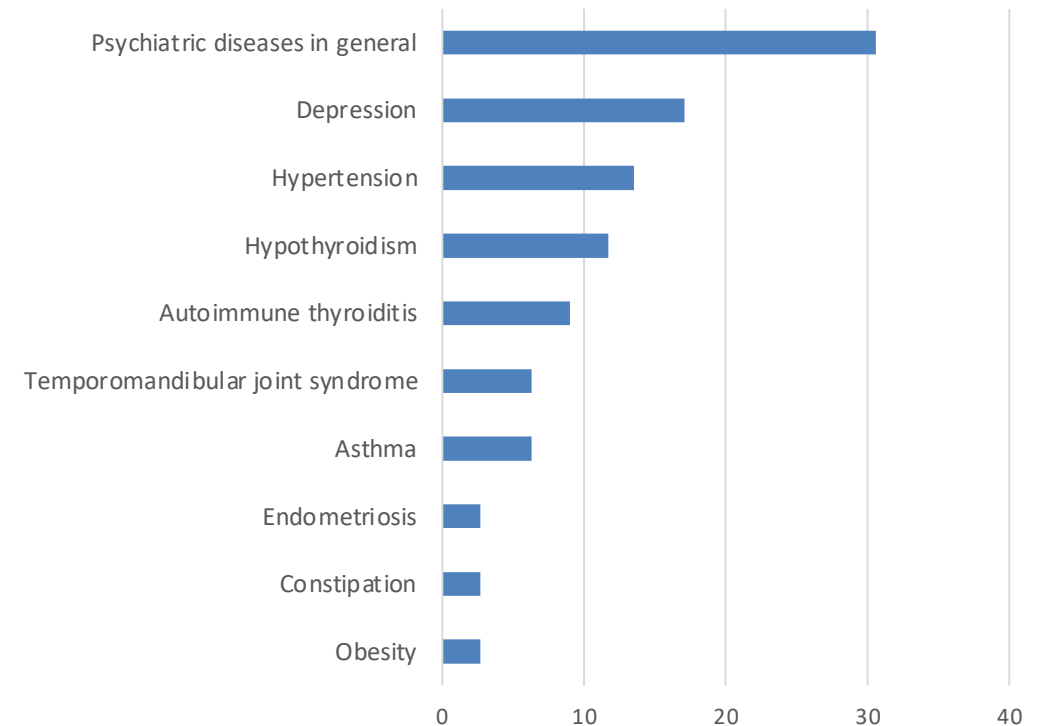
Results

At the time point for the interim data cut-off (30 January 2020), the baseline full analysis set included 111 patients enrolled in 35 centres

Characteristics	(n = 111)
Females, n (%)	99 (89,2)
Age, mean \pm SD	43,8 \pm 12,0
Years of migraine history, mean \pm SD	24,9 \pm 13,8
MMDs* mean \pm SD	10,5 \pm 5,3
Days with acute medication* mean \pm SD	10,3 \pm 5,5
Chronic migraine, n (%)	69 (62,6)
Acute medication overuse, n (%)	30 (27,8)

*during the last 3 months before initiation of Erenumab treatment
n=number of patients, SD=standard deviation, MMDs=monthly migraine days

Comorbidities (%)



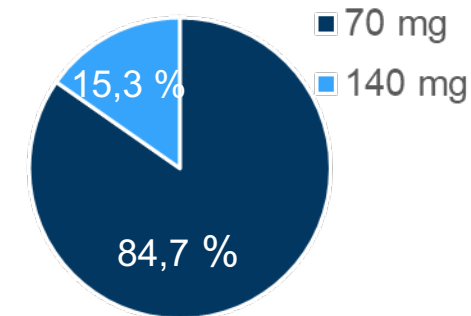


Previous Preventive Therapy

<i>Prophylaxis</i>	<i>n</i>	<i>%</i>
Total	111	100
Any prophylaxis	109	98,2
Topiramate	90	81.1
Amitryptiline	70	63.1
Flunarizine	56	50,5
Metoprolol	54	48.6
Onabotulinumtoxin A	38	34.2
Valproate	17	15.3
Propranolol	10	9.0
Candesartan	7	6.3
Bisoprolol	6	5.4
Venlafaxine	6	5.4

Erenumab Therapy

Starting dose



Main reason for choosing:

- 70 mg (n=94): 97,9 %:
following dose recommendation in the prescribing information
- 140 mg (n=17): 88,2 %:
due to severity of disease

Conclusion:

The SPECTRE study will give valuable insights into clinical practice of erenumab in Germany. This is the first interim analysis.