Design and population characteristics of patients treated with monoclonal antibody erenumab for assessment of long-term safety and tolerability and frequency of drug holidays in Germany (APOLLON)

S. Ortler[1], H. Göbel[2], M. Koch[1], M. Maier-Peuschel[1]

[1]Novartis Pharma GmbH, Nuremberg, Germany
[2]Schmerzklinik Kiel, Migräne- und Kopfschmerzzentrum, Germany

P10.047

BACKGROUND

- Erenumab was approved by FDA and EMA in 2018 as the first monoclonal antibody targeting the CGRP-receptor specifically developed for preventive migraine treatment.
- The long-term safety profile of erenumab has been investigated in open-label treatment phases of several global studies. Recently, 5-year data from an open-label trial confirmed the long-term safety profile of erenumab in an international cohort.
- However, data on long-term safety and efficacy in a large cohort of migraine patients in Germany is still limited.
- German guidelines for migraine preventive therapy (030/057 DGN/DMKG) suggest a re-evaluation of therapy and a drug holiday after 6-12 months of treatment if appropriate.
- Until now, there is a lack of comprehensive data on the impact of drug holidays for CGRP pathway antagonist antibodies.

OBJECTIVE

- Collection of long-term data for erenumab with respect to safety, tolerability and quality of life in patients with episodic or chronic migraine.
- Assess the relevance and impact of a drug holiday in patients previously treated with erenumab.

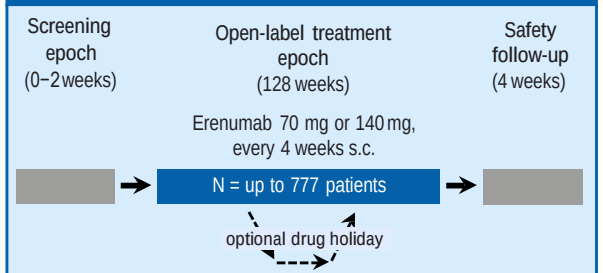
METHODS

- The APOLLON study (Assessment of Prolonged safety and tOLerability of erenumab in migraine patients in a Long-term OpeN-label study) is a 128-week, open-label study assessing long-term safety and tolerability of erenumab in migraine patients in Germany who previously participated in a 24-week, head-to-head trial comparing the tolerability of erenumab and topiramate (HER-MES, NCT03828539).
- At scheduled visits, the treating physician can change erenumab doses (70 mg or 140 mg) according to the approved label or initiate a drug holiday for up to 24 weeks.
- Thereby, impact of treatment discontinuation on monthly migraine days is assessed 4 weeks prior to, during and 12 weeks after the medication-free epoch. Impact of headache using the HIT-6 is measured throughout the study.

STUDYDESIGN

- The APOLLON study consists of three epochs (**Figure 1**):
  - **Screening epoch** lasting up to two weeks
  - **Open-label treatment epoch** lasting 128 weeks
    During the open-label treatment epoch, it is in the discretion of the treating physician to change the erenumab dose at each planned visit from 70 mg to 140 mg or vice versa.
    In addition, an optional drug holiday lasting up to 24 weeks can be initiated after at least twelve weeks of treatment.
  - **Follow-up epoch** lasting four weeks
    This epoch is part of routine safety monitoring.

Figure 1. Studydesign



s.c. = subcutaneous

RESULTS

- In total, 701 patients at 80 participating sites in Germany have been included in the APOLLON study, corresponding to 90.2% of all eligible patients, who were previously enrolled in the HER-MES study (**Figure 2**).
- Data shown on patient baseline characteristics are the result of an interim analysis with cut off date 14th of February 2021 and were collected prior to enrolling in HER-MES (**Table 1**):
  - mean age of included patients is 41 years
  - mean disease duration is 22.2 years,
  - on average patients are suffering from 11.5 headache days per month
  - on average patients are suffering from 10.4 migraine days per month

Figure 2. Proportion of patients rolling over from HER-MES to APOLLON study

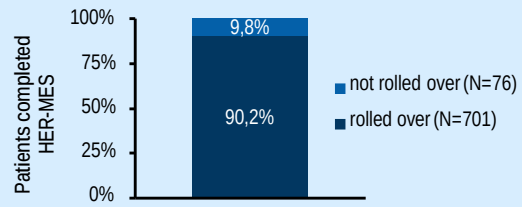


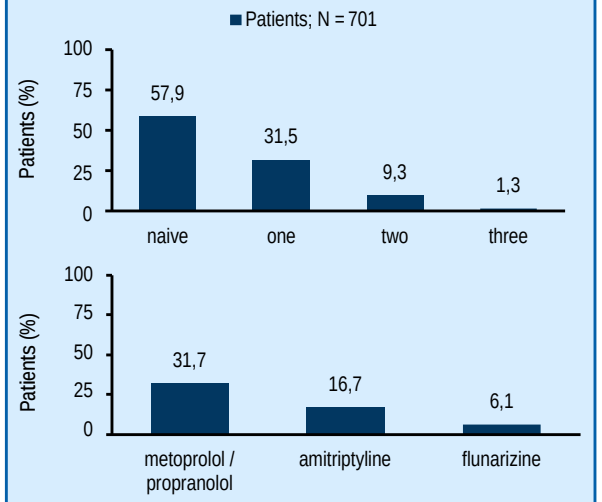
Table 1. Patient characteristics at study start

	Patients (N = 701)
Age (years)	41.0
Gender	
female, n (%)	608 (86.7%)
male, n (%)	93 (13.3%)
Weight (kg)	72.8
Disease duration (years)	22.2
Aura	
present, n (%)	238 (34.0%)
not present , n (%)	463 (66.0%)
Monthly headache days (days)*	11.5
Monthly migraine days (days)*	10.4
Stratification	
4-7 days, n (%)	165 (23.5%)
8-15 days, n (%)	471 (67.2%)
> 15 days, n (%)	65 (9.3%)

**Normalized to 28 days based on the number of days calculated in eDiary*

- About 58% of the patients did not receive any approved prophylactic migraine treatment (according to German migraine guidelines) and about 31% received only one prophylactic treatment (**Figure 3**).

Figure 3. Prior prophylactic treatments*



**Out of metoprolol/ propranolol, amitriptyline, flunarizine; prior treatment with topiramate, onabotulinum toxin A and valproic acid were excluded according to HER-MES study protocol*

CONCLUSION

- Presented data describe the study design and baseline characteristics of 701 patients included in the APOLLON study.
- The APOLLON study will provide data on long-term safety and tolerability of erenumab in patients with episodic and chronic migraine.

DISCLOSURE

S. Ortler and M. Maier-Peuschel are employees of Novartis Pharma GmbH.
M. Koch is employee of Novartis AG.
H. Göbel received honoraria for consulting and lectures from Allergan, Almirall, Astra Zeneca, Bayer Vital, Berlin-Chemie, Bionorica, Bristol-Myers-Squibb, Eli Lilly, Fujisawa, GlaxoSmithKline, Grünenthal, Hermal, Hormosan, Ipsen-Pharma, Janssen-Cilag, Johnson&Johnson, Krewel-Meuselbach, Klosterfrau, Lichtwer, Menarini Pharma, Merz Pharmaceuticals, Minster Pharmaceuticals, MSD, Novartis Pharma, Pfizer, Pharmacia, Sandoz, Schaper und Brümmer, Schwarz-Pharma, Teva, Weber&Weber, Smith Kline Beecham.

Funding source: This study is supported by Novartis Pharma GmbH, Nuremberg, Germany. Erenumab is co-developed by Amgen and Novartis.

(MLR ID: 119040)