

Design and population characteristics of APOLLON

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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

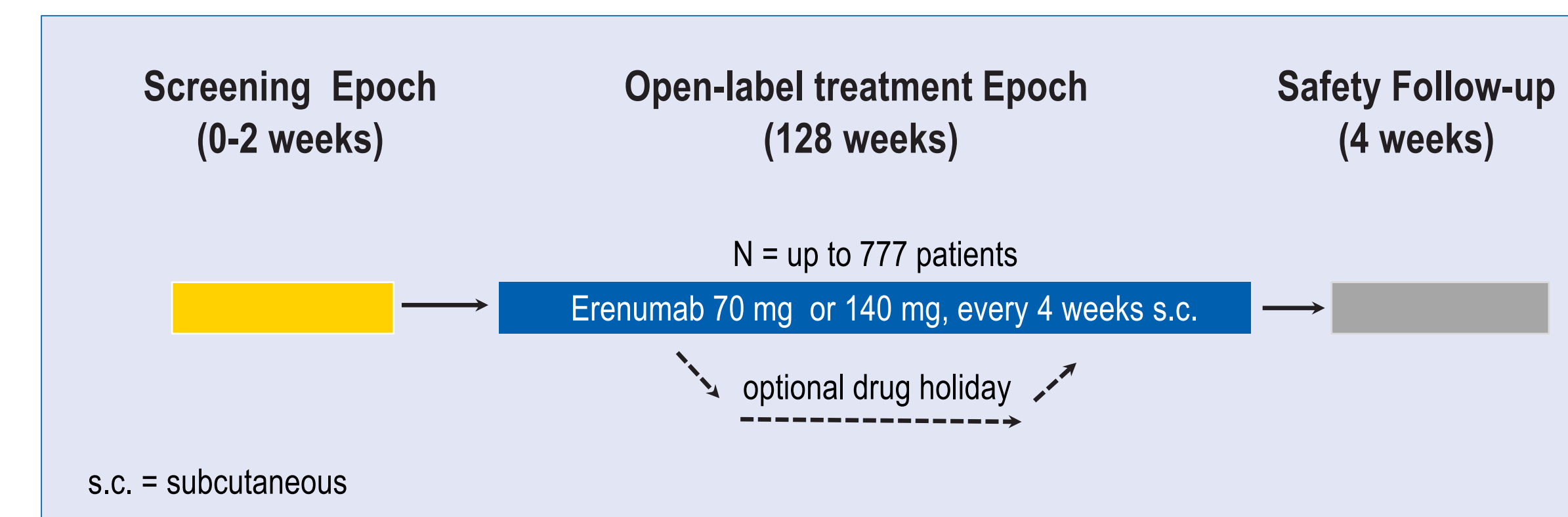
- The APOLLON study (Assessment of Prolonged safety and tOLerability of erenumab in migraine patients in a Long-term Open-label study) is a 128-week, open-label study assessing long-term safety and tolerability of erenumab in migraine patients in Germany who previously participated in a 24-week, head-to-head 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.

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Study design

- 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. Study design



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

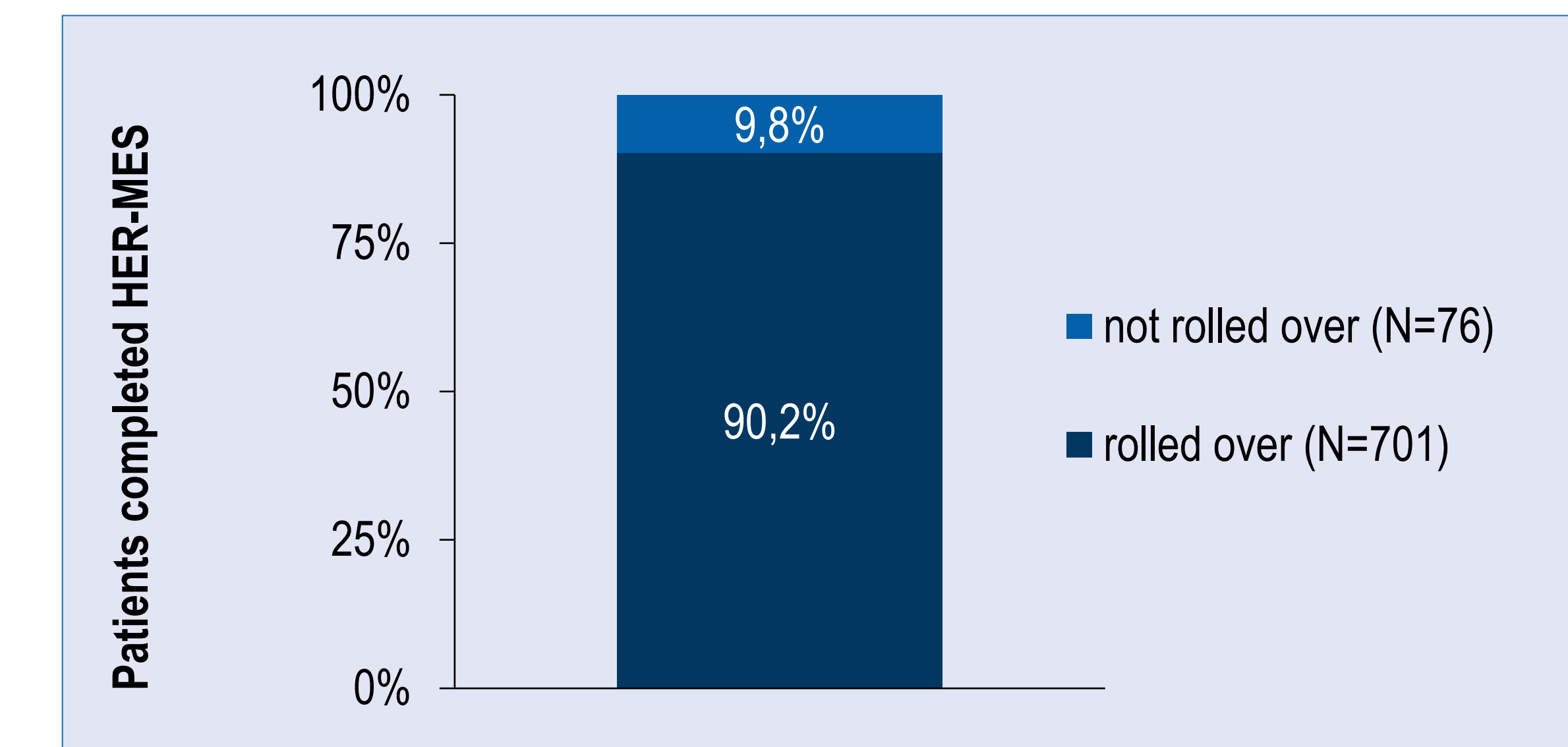


Table 1. Patient characteristics at study start

	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

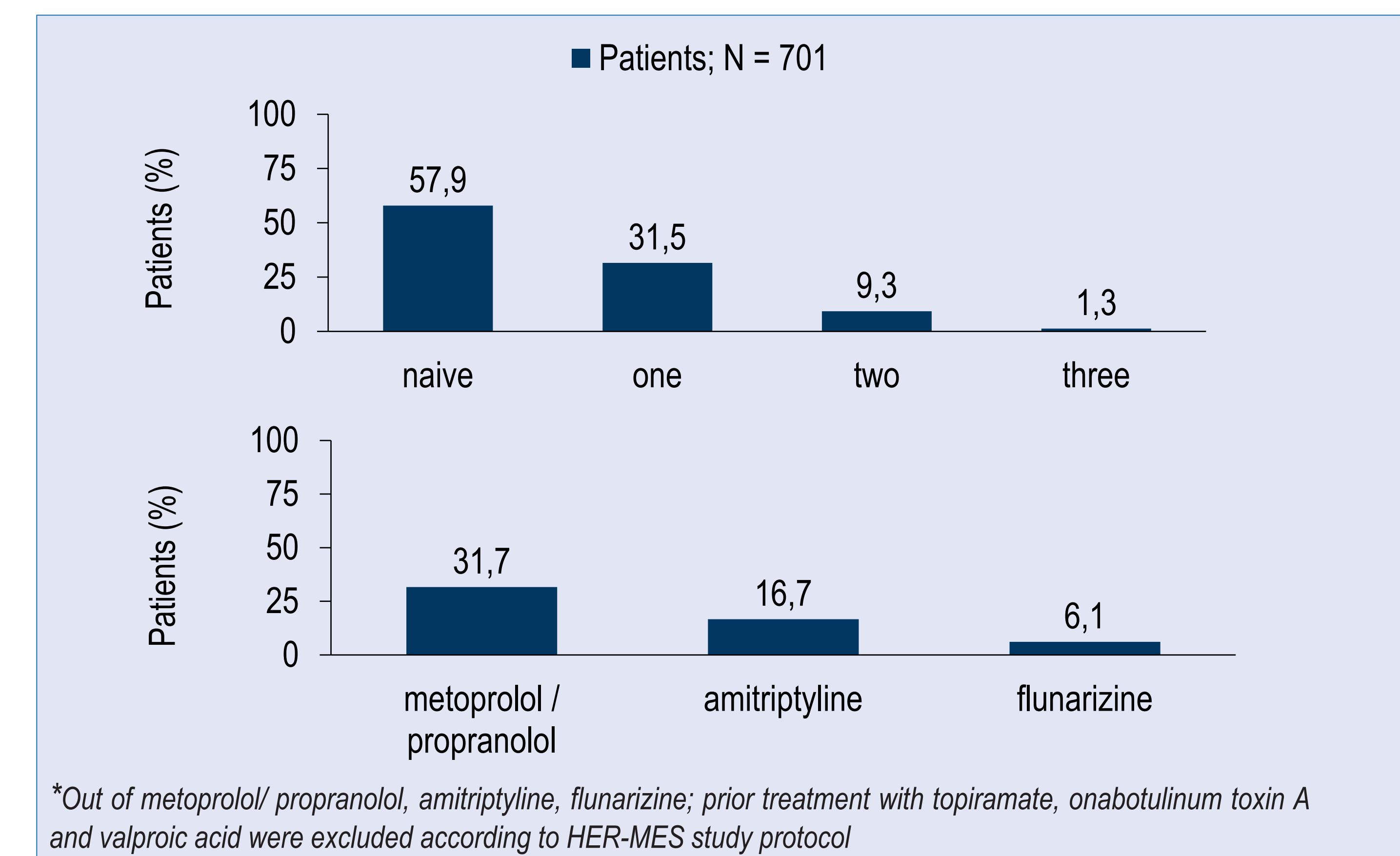
- About 58% of the patients did not receive any approved prophylactic migraine treatment (according to German migraine guidelines) and about 31% received only one prophylactic treatment (Figure 3).

CONCLUSIONS

- 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.

RESULTS (Continued)

Figure 3. Prior prophylactic treatments*



DISCLOSURES

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