Cardiovascular Safety of Erenumab in Patients With Migraine and Aura

Messoud Ashina,[1] Peter J Goadsby,[2] David W Dodick,[3] Stewart J Tepper,[4] Fei Xue,[5] Feng Zhang,[5] Jeffrey Olearczyk,[5] Gabriel Paiva da Silva Lima[5]

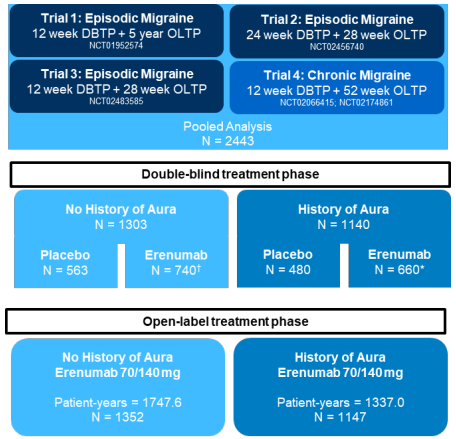
[1]Department of Neurology, Danish Headache Center, Rigshospitalet Glostrup, Faculty of Health and Medical Sciences, University of Copenhagen, Copenhagen, Denmark; [2]NIHR-Wellcome Trust King's Clinical Research Facility, King's College Hospital, London, UK; [3]Department of Neurology, Mayo Clinic, Scottsdale, AZ, USA; [4]Geisel School of Medicine at Dartmouth, Hanover, NH, USA; [5]Amgen Inc., Thousand Oaks, CA, USA

Objective

To evaluate cardiovascular and cerebrovascular safety of erenumab in patients with migraine and aura

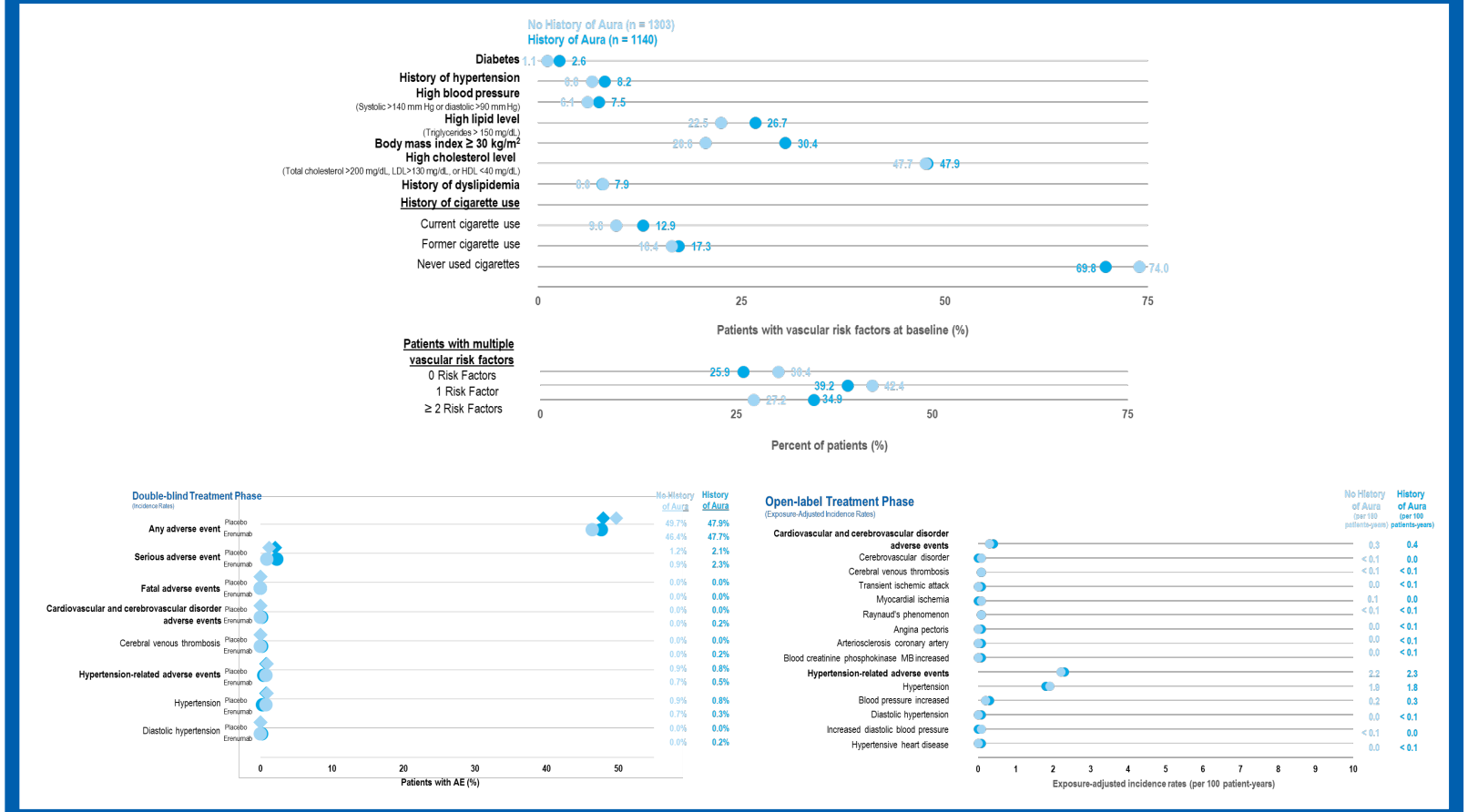
Methods

- Post hoc safety analysis of pooled data from four double-blind, placebo-controlled erenumab studies and their open-label extensions in patients with episodic and chronic migraine
- Subgroups defined based on history of aura status
- Double-blind treatment phase data used to assess overall safety profile by treatment group
- Open-label treatment phase data used to assess exposure-adjusted cardiovascular, cerebrovascular, and hypertension adverse events based on standardized MedDRA query (SMQ) version 20.0
  - Ischemic central nervous system vascular conditions SMQ
  - Ischemic heart disease SMQ
  - Peripheral arterial disease Amgen Medical Query (AMQ)
  - Hypertension SMQ



*429 patients received 70 mg and 231 received 140 mg; 77 patients received 7 or 21 mg every month not included in the DBTP analysis
†464 patients received 70 mg and 276 received 140 mg; 136 patients received 7 or 21 mg every month not included in the DBTP analysis
DBTP = double-blind treatment phase; OLTP = open-label treatment phase; analysis only includes 3-year interim data cut

The frequency of **cardiovascular and cerebrovascular** adverse events was **comparable between** patients with and without **aura** treated with **erenumab**, with **no increased** emergence of events **over time**.



Results

- Patients with and without history of aura had similar demographics and baseline disease characteristic histories
  - Baseline demographics were similar
    - across treatment groups within each aura subgroup and
    - between aura subgroups
  - Patients were mostly middle-aged (mean 41 years old) white (90%) women (84%), with a mean disease duration of 21 years and a mean of 11 monthly migraine days at baseline
  - Proportion of patients with prior or current migraine preventive medication treatment was slightly lower in the aura (47%) than the non-aura (57%) subgroup
- Vascular risk factors at baseline were more prominent in the aura subgroup
- Overall safety profiles were similar across treatment groups during the double-blind treatment phase regardless of aura history
- Cardiovascular, cerebrovascular, and hypertension adverse event rates through the open-label treatment phase were low with no differences between aura subgroups

Disclosures

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Fei Xue – Employee of and stockholder in Amgen
Feng Zhang – Employee of and stockholder in Amgen
Jeffrey Olearczyk– Employee of and stockholder in Amgen
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