

## **Changes in blood pressure category with erenumab: a pooled analysis of Phase 2 and Phase 3 clinical trials**

David W. Dodick<sup>1</sup>, Carrie Dougherty<sup>2</sup>, Kavita Kalidas<sup>3</sup>, Rob Nelson<sup>4</sup>, Nico Pannacciulli<sup>4</sup>, Fei Xue<sup>4</sup>, Feng Zhang<sup>4</sup>, Jose H. Flores-Arredondo<sup>4</sup>, Jessica Choudhry<sup>4</sup>

<sup>1</sup>Mayo Clinic, Scottsdale, AZ, USA; <sup>2</sup>MedStar Georgetown University Hospital, Washington, DC, USA;

<sup>3</sup>University of South Florida, Tampa, FL, USA; <sup>4</sup>Amgen Inc., Thousand Oaks, CA, USA

**One Sentence Summary:** Worsening of BP category was similar between erenumab and placebo.

**Background:** Erenumab (erenumab-aooe in the United States [US]) is a fully human monoclonal antibody that selectively targets and blocks the calcitonin gene-related peptide receptor to prevent migraine. In the US prescribing information for erenumab, there is a warning and precaution regarding new-onset or worsening of pre-existing hypertension (HTN) based on post-marketing experience. The objective of this analysis was to determine if erenumab treatment in clinical trials was associated with a worsening of blood pressure (BP) category compared with placebo in patients (pts) with normal BP, elevated BP, or HTN at baseline.

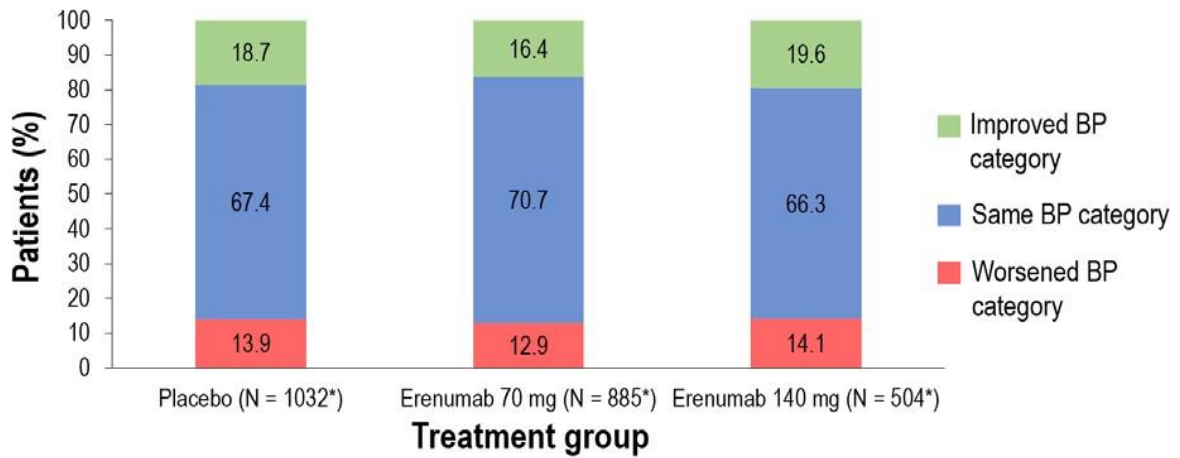
**Methods:** Data were pooled from two Phase 2 (NCT02066415 [12-week double-blind treatment phase (DBTP)] and NCT01952574 [12-week DBTP]) and two Phase 3 (NCT02456740 [24-week DBTP] and NCT02483585 [12-week DBTP]) clinical trials that evaluated erenumab 70 mg and 140 mg versus placebo for migraine prevention. Pts were grouped into the following American College of Cardiology/American Heart Association (ACC/AHA) guideline BP categories based on mean systolic BP (SBP) and mean diastolic BP (DBP) at screening and Day 1 (baseline) and during Months 1–3 of the DBTP: normal (SBP <120 mmHg and DBP <80 mmHg); elevated (SBP 120–129 mmHg and DBP <80 mmHg); Stage 1 HTN (SBP 130–139 mmHg or DBP 80–89 mmHg); or Stage 2 HTN (SBP ≥140 mmHg or DBP ≥90 mmHg). The primary outcome of this pooled analysis was the proportion of patients with a worsening of BP category over Months 1–3 of the DBTP relative to baseline.

**Results:** Overall, 1043, 893, and 507 pts received placebo, erenumab 70 mg, and erenumab 140 mg, respectively. Of pts with available post-baseline BP data (n=2421 [99.1%]), 53.5% of pts had elevated BP or Stage 1/2 HTN at baseline and the proportion of pts with elevated BP or Stage 1/2 HTN at baseline was well-balanced across treatment groups. There were no clinically relevant changes from baseline in mean SBP/DBP with erenumab 70 mg and 140 mg treatment compared with placebo during Months 1-3 of the DBTP. In pts with available post-baseline BP data, worsening of BP category from baseline to Months 1–3 of the DBTP occurred in 12.9% and 14.1% of pts treated with erenumab 70 mg and 140 mg, respectively, compared with 13.9% of pts who received placebo, while 70.7% and 66.3% of pts treated with erenumab 70 mg and 140 mg, respectively, remained in the same BP category compared with 67.4% of pts who received placebo (**Figure**). Of pts with elevated BP at baseline treated with erenumab 70 mg (n=108 [12.2%]) and 140 mg (n=68 [13.5%]), 30.6% and 29.4% of pts, respectively, had a worsening of BP to Stage 1/2 HTN over Months 1–3 of the DBTP, compared with 21.7% of pts with elevated BP at baseline who received placebo (n=129 [12.5%]). Of pts with Stage 1 HTN at baseline treated with erenumab 70 mg (n=281 [31.8%]) and 140 mg (n=160 [31.7%]), 8.2% and 5.6% of pts, respectively, progressed to Stage 2 HTN over Months 1–3 of the DBTP, compared with 11.6% of pts with Stage 1 HTN at baseline who received placebo (n=354 [34.3%]).

**Conclusions:** In clinical trials, worsening of ACC/AHA guideline BP category was similar between erenumab and placebo in pts with normal BP, elevated BP, or HTN at baseline. Additional data generation is warranted to further understand the risk of worsening BP in pts with migraine and pre-existing HTN treated with erenumab.

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**Figure.** Changes in ACC/AHA guideline BP Category from Baseline to Mean Over Months 1–3 of the DBTP.



\*Patients without post-baseline BP measurements were excluded. ACC/AHA guideline BP categories: normal (SBP <120 mmHg and DBP <80 mmHg); elevated (SBP 120–129 mmHg and DBP <80 mmHg); Stage 1 HTN (SBP 130–139 mmHg or DBP 80–89 mmHg); Stage 2 HTN (SBP ≥140 mmHg or DBP ≥90 mmHg). ACC, American College of Cardiology; AHA, American Heart Association; BP, blood pressure; DBP, diastolic blood pressure; DBTP, double-blind treatment phase; HTN, hypertension; SBP, systolic blood pressure.

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