Eptinezumab for the Prevention of Episodic Migraine Through 1 Year: Results from the Phase 3 PROMISE-1 (PRevention Of Migraine via Intravenous Eptinezumab Safety and Efficacy–1) Trial

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Disclosures

Relevant: *Advisory board and/or speaker*: Alder BioPharmaceuticals; *Research support*: Alder BioPharmaceuticals

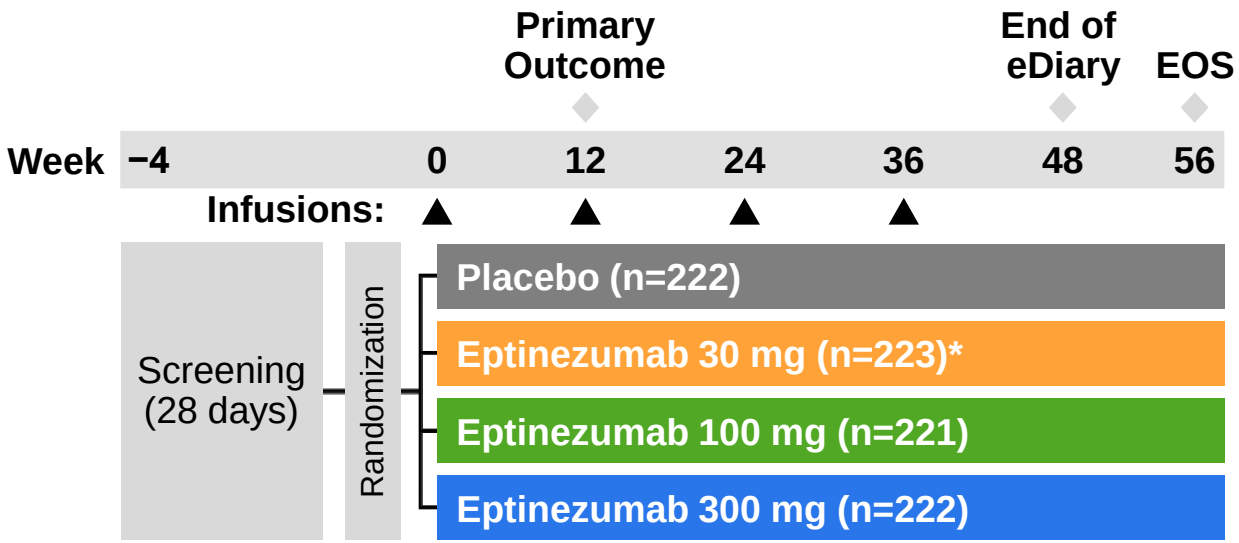
Other: *Advisory board and/or speaker*: Autonomic Technologies, Biohaven Pharmaceuticals, Eli Lilly, Teva Pharmaceuticals. *Research support*: Allergan, Amgen, Avanir Pharmaceuticals, Autonomic Technologies, Biohaven Pharmaceuticals, Colucid Pharmaceuticals, Dr. Reddy's Laboratories, Eli Lilly, Impax Pharmaceuticals, Scion NeuroStim, Teva Pharmaceuticals, Zosano Pharma

PROMISE-1: phase 3, multicenter, parallel-group, double-blind, randomized, placebo-controlled trial (NCT02559895)

Eptinezumab (ALD403) is an IgG1 anti-CGRP monoclonal antibody administered quarterly by IV infusion, allowing for 100% bioavailability at the end of infusion

Inclusion/Exclusion Criteria

- Patients aged 18–75 yrs
- Diagnosis of migraine (ICHD-II) at age ≤50 yrs
- 4–14 headache days/month, including ≥4 migraine days/month in previous 12 months and during screening period
- No use of botulinum toxin or prophylactic headache medications prior to (4 and 2 months, respectively) or during the screening period



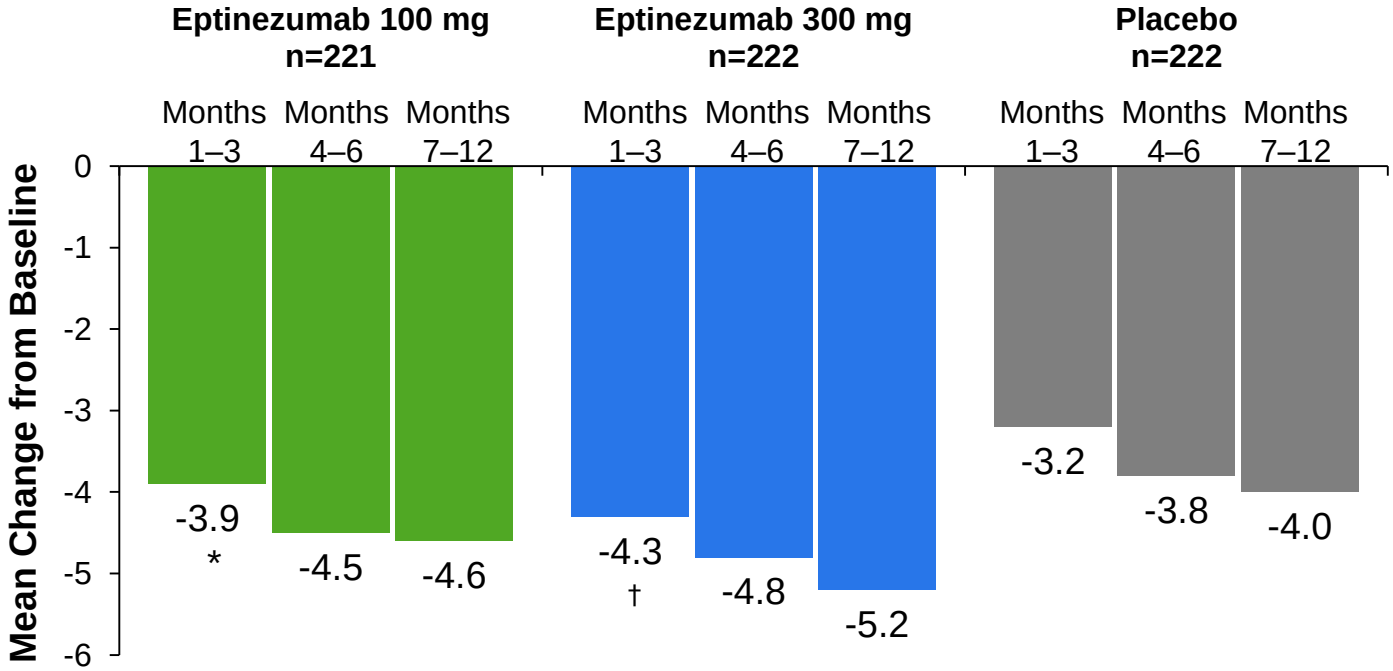
EOS, end of study. *Results not presented because all endpoints for this dose were considered not significant due to to the multiplicity procedure

Eptinezumab 100 mg and 300 mg met the primary efficacy endpoint

Primary Endpoint: Change from Baseline in MMDs over Months 1–3

Baseline:
~8.6 MMDs

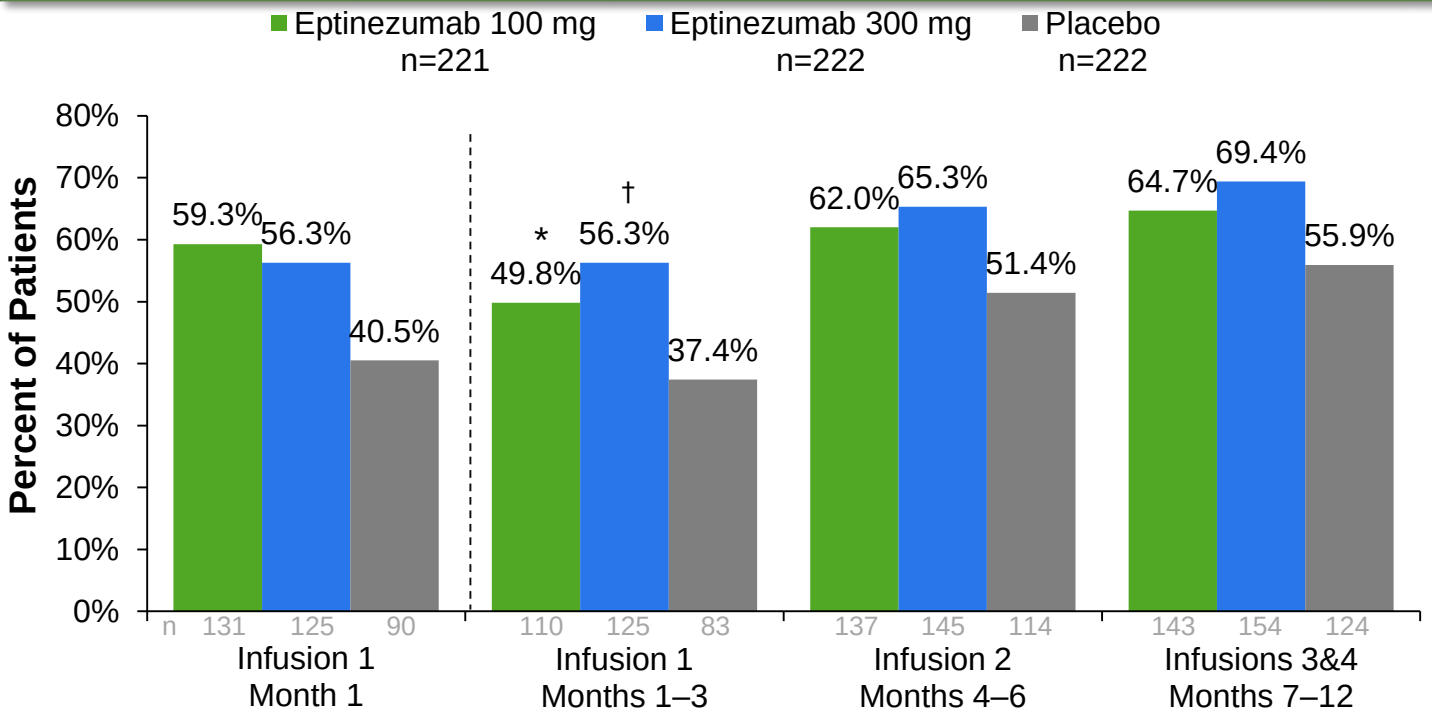
Eptinezumab significantly reduced the frequency of monthly migraine days vs placebo during the first quarterly infusion period



MMDs, monthly migraine days. *p=0.0182; †p=0.0001 vs placebo. Months 4–6 and 7–12 were not included in the prespecified statistical algorithm. For eptinezumab 30 mg (n=223), the change from baseline was –4.0 over Months 1–3 (p=0.0046; unadjusted) and –5.0 over Months 10–12

Eptinezumab demonstrated early and robust reductions in monthly migraine frequency: ≥50% migraine responder rates (MRRs)

Key Secondary Endpoint: ≥50% MRRs over Months 1–3

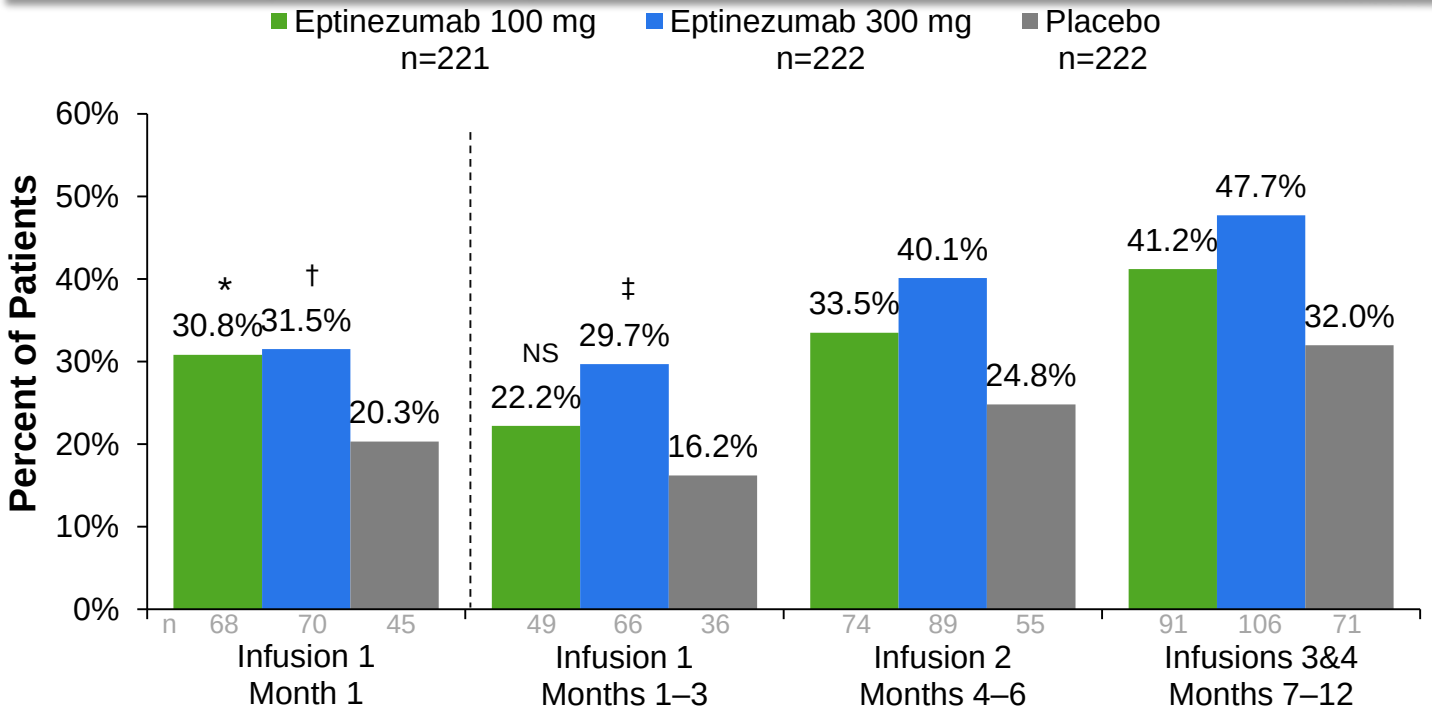


Significantly more eptinezumab-treated patients achieved ≥50% reduction in monthly migraine days vs placebo during the first quarterly infusion period

*p=0.0085 (unadjusted); †p=0.0001 vs placebo. Months 1, 4–6, and 7–12 were not included in the prespecified statistical algorithm.

Eptinezumab demonstrated early and robust reductions in monthly migraine frequency: ≥75% migraine responder rates (MRRs)

Key Secondary Endpoints: ≥75% MRRs over Months 1 and 1–3

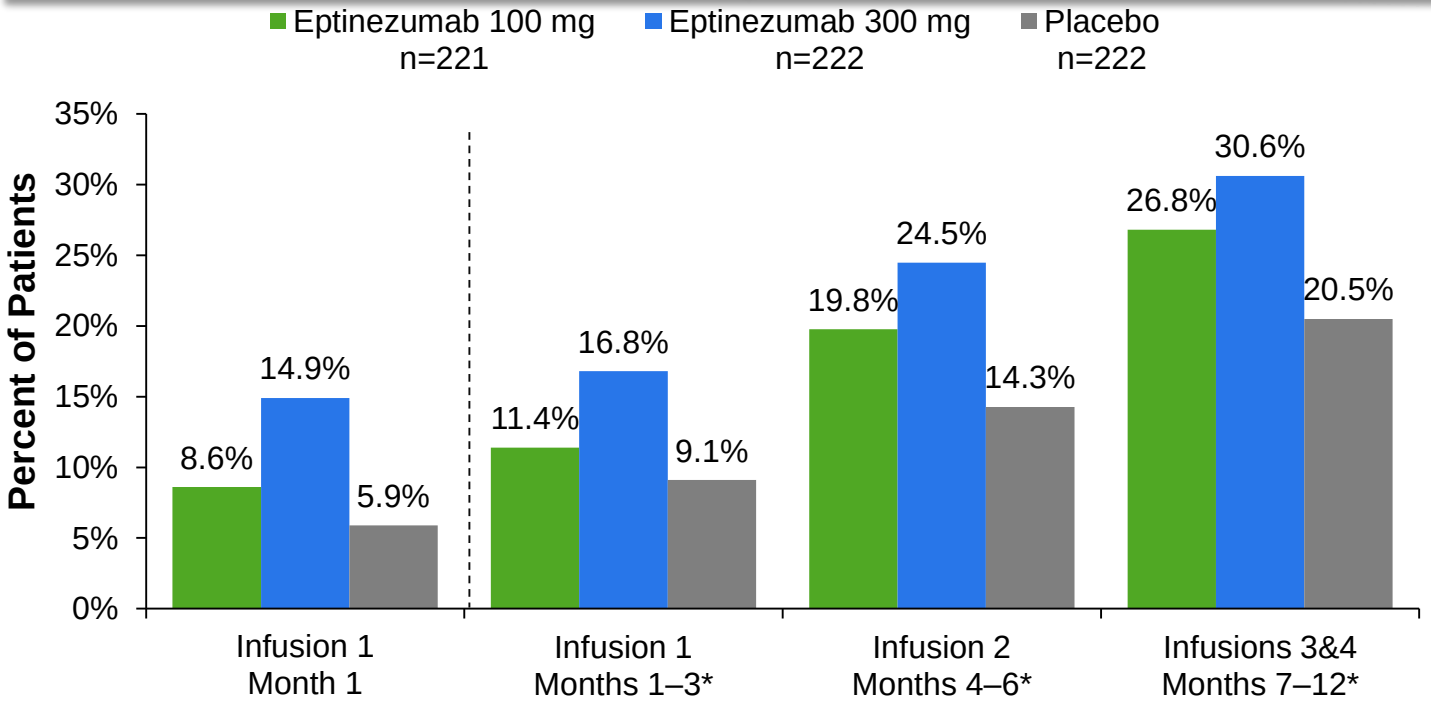


Significantly more eptinezumab-treated patients achieved ≥75% reduction in monthly migraine days vs placebo by Month 1 and during Months 1–3 (for 300 mg)

*p=0.0112; †p=0.0066; ‡p=0.0007 vs placebo. NS, not significant. Months 4–6 and 7–12 were not included in the prespecified statistical algorithm.

Eptinezumab demonstrated early and robust reductions in monthly migraine frequency: 100% migraine responder rates (MRRs)*

Secondary Endpoint: 100% MRRs*

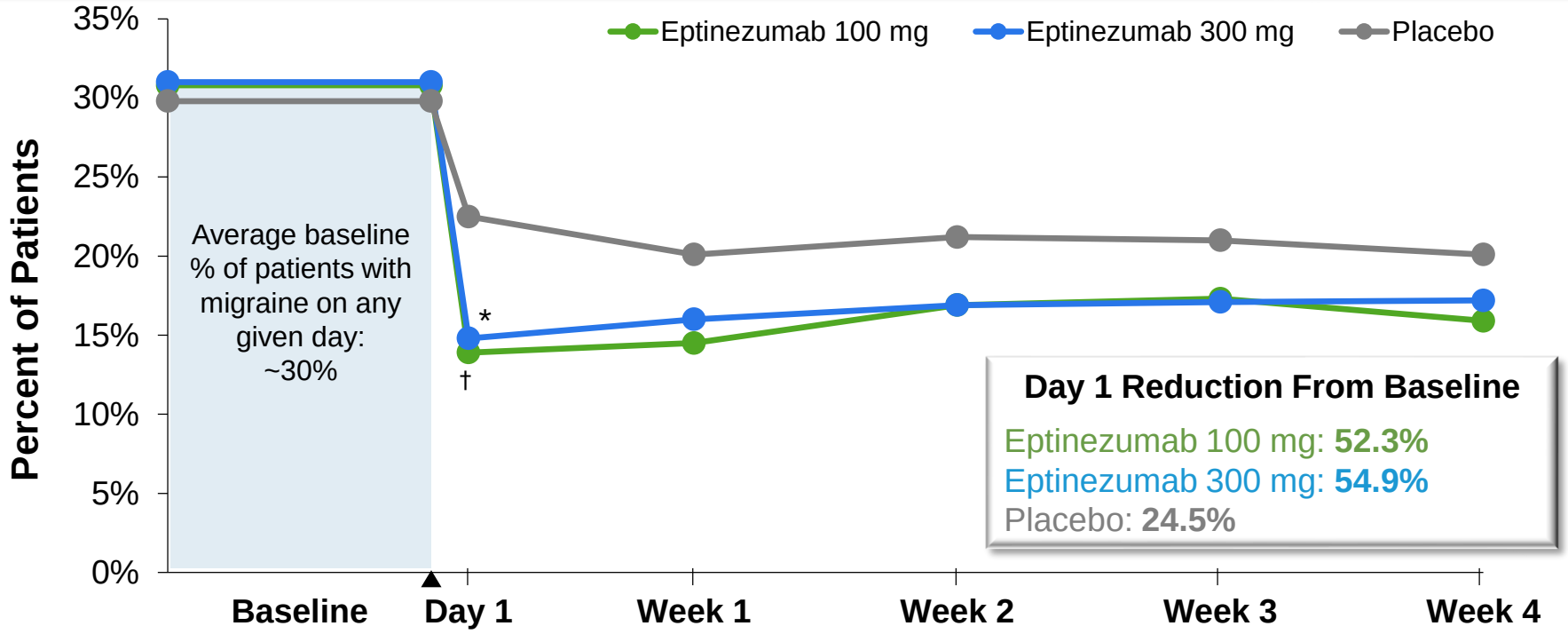


More eptinezumab-treated patients achieved 100% reduction in monthly migraine days vs placebo

*Calculated as the average percentage of patients with 100% response for any given month during the infusion period. 100% MRRs were not included in the prespecified statistical algorithm.

Eptinezumab reduced the percentage of patients with a migraine by >50% on Day 1 compared with the average daily percentage during the baseline period

Key Secondary Endpoint: Percentage of Patients with a Migraine on Day 1



*p=0.0159 vs placebo, unadjusted; †p=0.0312 vs placebo, unadjusted.

Eptinezumab treatment demonstrated acceptable safety and tolerability across doses as compared to placebo

Patients, n (%)	Eptinezumab 30 mg n=224	Eptinezumab 100 mg n=223	Eptinezumab 300 mg n=219	Placebo n=222
Any TEAE	128 (58.4%)	141 (63.2%)	129 (57.6%)	132 (59.5%)
Serious	4 (1.8%)	4 (1.8%)	3 (1.3%)	6 (2.7%)
Treatment-related*	24 (11.0%)	28 (12.6%)	32 (14.3%)	19 (8.6%)
Leading to treatment discontinuation	12 (5.5%)	6 (2.7%)	5 (2.2%)	6 (2.7%)
Most common TEAEs†				
Upper respiratory tract infection	25 (11.4%)	22 (9.9%)	23 (10.3%)	16 (7.2%)
Nasopharyngitis	14 (6.4%)	17 (7.6%)	14 (6.3%)	12 (5.4%)
Sinusitis	7 (3.2%)	6 (2.7%)	11 (4.9%)	14 (6.3%)

TEAE, treatment-emergent adverse event. *As determined by the principal investigator. †Occurring in ≥5% of patients in any treatment group.

Conclusions

- Eptinezumab 100 mg and 300 mg met the primary efficacy endpoint, the mean change from baseline in mean MMDs over the first infusion period (Months 1–3) vs placebo
- The magnitude of migraine responder rates for ≥50%, ≥75% and 100% over the first infusion period was increased over the course of the study through the fourth infusion period
- Robust response at Month 1 after treatment with eptinezumab was achieved by its rapid onset on action, with a ≥50% reduction in the percentage of patients with a migraine on Day 1 after treatment
- Eptinezumab treatment was generally safe and well tolerated across doses

MMDs, monthly migraine days.