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A phase 3, randomised, double-blind, placebo-controlled study to evaluate the efficacy and safety of erenumab in migraine prevention: primary results of the arise trial

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Abstract

Objectives Efficacy and safety of erenumab, a human anti-calcitonin gene-related peptide (CGRP) receptor monoclonal antibody, were evaluated in patients with episodic migraine (EM) in a phase 3 trial (NCT02483585).

Methods Five-hundred and seventy seven adults with EM were randomised 1:1 to subcutaneous, monthly placebo or erenumab (70 mg). Primary endpoint was change in monthly migraine days (MMDs) from baseline to weeks 9–12 of a 12 week double-blind phase. Secondary endpoints were achievement of ≥50% reduction in MMDs, change in acute migraine-specific medication use, and ≥5-point reduction in Physical Impairment (PI) and Impact on Everyday Activities (EA) measured by the Migraine Physical Function Impact Diary. Statistical significance was determined after adjustment for multiple comparisons.

Results Patients reported a mean 8.3 MMDs at baseline. Those receiving erenumab experienced a mean −2.9 day change (reduction) from baseline in MMDs, compared with a -1.8 day reduction for placebo ($p<0.001$). A≥50% reduction in MMDs was achieved by 40% and 30% in erenumab and placebo groups

(OR: 1.6; p=0.010). Monthly acute migraine-specific medication use was reduced by mean −1.2 and −0.6 days (p=0.002). Respective ≥5-point reductions (improvement) in PI were achieved by 33% and 27% of patients (p=0.13) and in EA by 40% and 36% (p=0.26). The safety profile of erenumab was similar to placebo. Most frequently reported AEs across both groups were upper respiratory tract infection, injection site pain and nasopharyngitis.

Conclusions Erenumab statistically significantly reduced migraine frequency, acute migraine-specific medication use and a greater proportion of patients achieved ≥50% reduction in MMDs, compared with placebo, in this phase 3 trial in EM.

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