Erenumab Versus Topiramate for the Prevention of Migraine: Results of a Randomised Active-controlled Double-dummy Trial

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Introduction:

Erenumab (erenumab-aooe in the US) is a fully human monoclonal antibody that inhibits the calcitonin gene-related peptide (CGRP) receptor and approved by the Food & Drug Administration and European Medicines Agency as the first medication specifically developed for migraine prevention. HER-MES is the first Head-to- head study of Erenumab against topiRamate-Migraine study to assess tolerability and efficacy in a patiEnt-centered Setting (NCT03828539).

Methods:

In this 24-week double-blind, double-dummy treatment epoch (DBTE), a German cohort of 777 adult migraine patients with >=4 monthly migraine days (MMD) received either erenumab 70 mg or 140 mg/month subcutaneously (investigator's choice) and an oral placebo or a subcutaneous placebo and the maximum tolerated dose of oral topiramate (50–100 mg/day; control group). The primary endpoint of tolerability was assessed by the rate of treatment discontinuation due to adverse events (AEs). The secondary endpoint addressing efficacy was assessed by the proportion of patients achieving >=50% reduction from baseline MMD over Months 4, 5, and 6.

Results:

Both primary and secondary endpoints were met, showing a significant difference between erenumab and topiramate. During the DBTE, 10.6% of patients receiving erenumab and 38.9% of patients receiving topiramate discontinued study treatment due to AEs. Additionally, the 50% responder rate was significantly higher for erenumab compared to topiramate.

Conclusion:

The results of this first head-to-head trial of a therapy targeting the CGRP pathway compared to a preventive standard-of-care therapy will provide guidance for clinical decision-making for the preventive treatment of migraine.