

POSTER PRESENTATION

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OnabotulinumtoxinA for treatment of chronic migraine: PREEMPT 24-week pooled subgroup analysis of patients without medication overuse

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Introduction

CM is a prevalent, disabling primary headache disorder. Most patients in CM clinical trials overuse AHM. The efficacy of prophylactic medications in CM patients without overuse of AHM is unclear.

Objective

To evaluate the efficacy and tolerability of onabotulinumtoxinA in a chronic migraine (CM) subgroup without acute headache medication (AHM) overuse (MO-No).

Design/methods

PREEMPT (two phase 3 studies: 24-week, double-blind, placebo-controlled, parallel-group phase, followed by 32-week, open-label phase) evaluated onabotulinumtoxinA for prophylaxis of headaches in CM (≥ 15 days/month with headache lasting ≥ 4 hours/day). Patients were stratified based on AHM use during 28-day baseline and randomized (1:1) to onabotulinumtoxinA (155-195U) or placebo every 12 weeks. Multiple headache-symptom measures were evaluated at Week 24, including mean change from baseline in headache-day frequency (primary). Pooled results from MO-No subgroup are reported.

Results

480 (n=243 onabotulinumtoxinA; n=237 placebo) of 1384 patients met MO-No criteria. At Week 24, onabotulinumtoxinA treatment significantly reduced headache-day frequency compared to placebo (-8.8/onabotulinumtoxinA; -7.3/placebo; p=0.013). Significant improvements from baseline (p \leq 0.027) also favored onabotulinumtoxinA at Week 24 for frequency of migraine-days, moderate/severe

headache-days, total cumulative hours of headache on headache-days, and percent of patients with severe (≥ 60) headache impact test (HIT-6) scores. Improvements in total HIT-6 and migraine-specific questionnaire scores all significantly favored onabotulinumtoxinA over placebo at Week 24 (p \leq 0.032). Few patients in this subgroup discontinued because of an adverse event (AE); AEs were consistent with overall PREEMPT tolerability.

Conclusion/relevance

OnabotulinumtoxinA is effective and well-tolerated for prophylaxis of headache in CM patients who do not overuse AHM.

Support

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