

Impact of Fremanezumab on the Number of Days With Use of Acute Headache Medication in Chronic Migraine

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Introduction: Overuse of acute headache medication is common in people with chronic migraine (CM) and can lead to worsening of headache. Fremanezumab, a fully humanized monoclonal antibody (IgG2 Δ a) selectively targeting calcitonin gene-related peptide (CGRP), has demonstrated efficacy in migraine prevention in adults. The goal of this study was to evaluate whether, in addition to reducing headache day frequency, fremanezumab impacts use of acute headache medication. **Methods:** In a Phase 3, multicenter, randomized, double-blind, placebo-controlled parallel-group study, eligible adult patients with prospectively confirmed CM (≥ 15 headache days and ≥ 8 migraine days per month) were randomized 1:1:1 to receive subcutaneous injections of fremanezumab quarterly (675 mg at baseline; placebo at Weeks 4 and 8), fremanezumab monthly (675 mg at baseline; 225 mg at Weeks 4 and 8), or placebo over a 12-week treatment period. The monthly number of days on which patients used acute headache medication were evaluated as secondary and exploratory endpoints. **Results:** 1130 patients were randomized (quarterly, n=376; monthly, n=379; placebo, n=375). The monthly number of days with use of any acute headache medication was significantly reduced from baseline in both fremanezumab regimens (quarterly: -3.7 ± 0.30 days; monthly: -4.2 ± 0.30 days) versus placebo (-1.9 ± 0.30 days) during the 12-week treatment period (both, $P < 0.0001$), with significant reductions observed as early as Week 4 (quarterly: -3.9 ± 0.31 days; monthly: -4.1 ± 0.31 days; placebo: -1.6 ± 0.31 days) and at each time point thereafter (all, $P < 0.001$). Likewise, fremanezumab significantly reduced the use of migraine-specific acute headache medication (quarterly: -3.3 ± 0.35 days; monthly: -3.9 ± 0.35 days) versus placebo (-1.1 ± 0.36 days) over the 12-week period (both, $P < 0.0001$). These effects were observed as early as Week 4 and sustained until the end of the trial (all, $P < 0.0001$). **Conclusions:** Fremanezumab reduces the need for use of acute headache medication, including migraine-specific medication, in patients with CM.