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OR09: A phase 2b randomized, double-blind, placebocontrolled trial of ubrogepant for acute treatment of a migraine attack

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Background: The aim of this trial was to evaluate the efficacy and tolerability of ubrogepant (MK-1602), a calcitonin gene_related peptide (CGRP) receptor antagonist, for the acute treatment of migraine.

Methods: This was a Phase 2b randomized, placebo controlled, double-blind trial. A total of 834 migraine patients were randomized to treat a single migraine attack with ubrogepant 1 mg, 10 mg, 25 mg, 50 mg, 100 mg, or placebo in a 1:1 ratio. The co-primary endpoints were pain freedom and headache response (reduction in headache severity from severe or moderate at baseline to mild or none) at 2 hours. The first hypothesis tested the dose-response trend for 2-hour pain freedom and was assessed using a logistic regression model. Subsequent hypotheses tested the effects of each dose on the co-primary endpoints, using a closed sequential testing procedure to control for multiplicity.

Results: A total of 640 patients received study medication: 527 received ubrogepant (1 mg, n5107; 10 mg, n5108; 25 mg, n5104; 50 mg, n5106; 100 mg, n5102), and 113 received placebo. There was a positive response trend across ubrogepant doses as measured by the proportion of participants who achieved 2-hour pain freedom ($p<0.001$ for trend test). Ubrogepant 100 mg was significantly superior to placebo for 2-hour pain freedom (25.8% vs 8.9%) but not for the 2-hour headache response endpoint. This non-significant result precluded further hypothesis testing per the multiplicity strategy. Overall adverse events were similar between ubrogepant and placebo.

Conclusion: This trial supports ubrogepant's efficacy and provides further evidence that CGRP receptor antagonists are viable options for the acute treatment of migraine.

Reprinted from the 58th Annual Scientific Meeting of the American Headache Society, held June 9–12, 2016, in San Diego, California.