

## CONFERENCE COVERAGE

## Ubrogapant May Treat Acute Migraine Attacks Effectively

**The novel CGRP receptor antagonist reduces pain and symptoms such as photophobia and nausea, compared with placebo.**

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**LOS ANGELES**—Ubrogapant may relieve the pain of acute migraine attacks, as well as other bothersome migraine-related symptoms, according to data presented at the 70th Annual Meeting of the American Academy of Neurology. The drug is well-tolerated and does not raise significant safety concerns, according to the researchers.

Ubrogapant is a novel, oral antagonist of the calcitonin gene-related peptide (CGRP) receptor that Allergan is developing for the acute treatment of migraine. Joel Trugman, MD, Director of Clinical Development for Allergan, and colleagues conducted a phase III study to examine the efficacy, safety, and tolerability of ubrogapant, compared with placebo, for the acute treatment of a single migraine attack.

### Assessing Two Doses of Ubrogapant

In this multicenter, double-blind, parallel-group study, adult patients with a history of migraine with or without aura were randomized in equal groups to placebo, 50 mg of ubrogapant, or 100 mg of ubrogapant. Patients had as many as 60 days to treat a single migraine attack of moderate or severe headache pain intensity. The study's two primary efficacy end points were pain freedom at two hours after initial dose and absence of the most bothersome migraine-associated symptom (MBS) at two hours after initial dose. Participants identified the MBS at the time of the treated attack. The investigators also assessed ubrogapant's safety and tolerability.

Dr. Trugman and colleagues randomized 1,672 patients. Of this population, 1,436 participants were included in the safety population, and 1,327 were included in the modified-intention-to-treat efficacy analysis. The latter efficacy analysis included patients who received one or more dose of ubrogapant,

recorded baseline headache severity, and recorded one or more postdose headache severity or MBS measurement at or before two hours.

## Ubrogепant Was Superior to Placebo

The population's mean age was 40.7. Most participants were Caucasian (82.4%) and female (87.5%). The MBS identified at the time of treatment were photophobia (56.4%), phonophobia (22.3%), and nausea (20.9%). At two hours after the initial dose, the percentage of patients achieving pain freedom was 19.2% for the 50-mg group, 21.2% for the 100-mg group, and 11.8% for controls. The percentage of patients achieving absence of MBS was 38.6% for the 50-mg group, 37.7% for the 100-mg group, and 27.8% for controls. The differences between the active and control groups were statistically significant for both end points.

Ubrogепant also yielded significantly improved results on secondary end points, compared with placebo. Approximately 61% of patients who took ubrogепant achieved pain relief at two hours, compared with 49% of controls. About 36% of patients in the 50-mg group and 38% of patients in the 100-mg group achieved sustained pain relief at two to 24 hours, compared with 21% of controls. In addition, the 100-mg dose of ubrogепant yielded statistically significant differences on sustained pain freedom at two to 24 hours and on absence of photophobia at two hours, compared with placebo.

The adverse-event profile of ubrogепant was similar to that of placebo. The most common adverse events within 48 hours of dosing were nausea, somnolence, and dry mouth. The incidence of each of these adverse events was less than 5%.

This study was supported by Allergan.

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