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Allergan gets FDA nod for acute migraine treatment

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It is the first drug in the class of oral calcitonin gene-related peptide receptor antagonists approved for the acute treatment of migraine

The U.S. Food and Drug Administration has approved Ubrelvy (ubrogepant) tablets for the acute (immediate) treatment of migraine with or without aura (a sensory phenomenon or visual disturbance) in adults. Ubrelvy is not indicated for the preventive treatment of migraine. It is the first drug in the class of oral calcitonin gene-related peptide receptor antagonists approved for the acute treatment of migraine.

"Migraine is an often disabling condition that affects an estimated 37 million people in the U.S.," said Billy Dunn, M.D., acting director of the Office of Neuroscience in the FDA's Center for Drug Evaluation and Research. "Ubrelvy represents an important new option for the acute treatment of migraine in adults, as it is the first drug in its class approved for this indication. The FDA is pleased to approve a novel treatment for patients suffering from migraine and will continue to work with stakeholders to promote the development of new safe and effective migraine therapies."

Migraine headache pain is often described as an intense throbbing or pulsating pain in one area of the head. Additional symptoms include nausea and/or vomiting and sensitivity to light and sound. Approximately one third of individuals who suffer from migraine also experience aura shortly before the migraine. An aura can appear as flashing lights, zig-zag lines, or a temporary loss of vision. Migraines can often be triggered by various factors including stress, hormone changes, bright or flashing lights, lack of food or sleep and diet. Migraine is three times more common in women than in men and affects more than 10% of people worldwide.

The effectiveness of Ubrelvy for the acute treatment of migraine was demonstrated in two randomized, double-blind, placebo-controlled trials.

The FDA granted the approval of Ubrelvy to Allergan USA, Inc.