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Single Dose of Rimegepant Shows Durable Effects in Acute Treatment of Migraine

Rimegepant may be a novel approach to the acute treatment of migraine.

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SAN FRANCISCO—Among patients with migraine, significant and durable clinical effects were seen with a single dose of rimegepant across multiple outcome measures, including pain freedom, freedom from most bothersome symptom, pain relief, and recovery of normal function, according to data presented at the 60th Annual Scientific Meeting of the American Headache Society. Rimegepant (75 mg oral tablet) demonstrated favorable tolerability and safety, including a liver safety profile, similar to placebo. "These clinically meaningful results complement the benefits seen in an identical phase III study and a previous phase IIb study," said Richard B. Lipton, MD, Edwin S. Lowe Chair in Neurology at Albert Einstein College of Medicine in New York, and colleagues. "Rimegepant may ultimately offer patients a novel approach for the acute treatment of migraine."

Dr. Lipton and colleagues conducted a double-blind, randomized, placebo-controlled trial to compare the efficacy, safety, and tolerability of the calcitonin gene-related peptide (CGRP) receptor antagonist rimegepant (75 mg oral tablet) with placebo in the acute treatment of migraine in adults.

Richard B. Lipton, MD

The study included adults 18 or older with at least a one-year history of migraine according to ICHD 3-beta criteria. Following a three- to 28-day screening period, subjects were randomized to receive 75 mg of rimegepant or placebo and instructed to treat a single migraine attack with one

dose of the blinded study drug (ie, rimegepant or placebo) when headache pain reached moderate or severe intensity. The coprimary end points were pain freedom at two hours postdose and freedom from the most bothersome symptom at two hours postdose. Safety assessments included adverse events, ECGs, vital signs, physical measurements, and routine laboratory tests, including assessment of liver function.

In total, 1,162 subjects were randomized to receive rimegepant (n = 582) or placebo (n = 580), and 1,084 were evaluated for efficacy (rimegepant [n = 543], placebo [n = 541]). Subjects had a mean age of 41.6, 85.5% were female, and participants by history averaged 4.7 attacks per month. At two hours postdose, rimegepant-treated patients had higher pain-free rates than placebo-treated patients did (19.2% vs 14.2%, respectively), were more likely to be free of their most bothersome symptom (36.6% vs 27.7%, respectively), and had higher rates of pain relief (56.0% vs 45.7%, respectively).

A single dose of rimegepant, without the use of rescue medication, demonstrated superiority versus placebo for sustained pain freedom and pain relief from two through 48 hours postdose. On a measure of functional disability, a greater proportion of rimegepant-treated patients achieved normal function at two hours. The safety and tolerability profiles of rimegepant were similar to those of placebo. The most common adverse events in the rimegepant and placebo groups were nausea (0.9% [5 of 546] vs 1.1% [6 of 549], respectively) and dizziness (0.7% [4 of 546] vs 0.4% [2 of 549], respectively).

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