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AbbVie Secures EC Approval for AQUIPTA as Acute Migraine Treatment

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The approval gives atogepant a second European indication, positioning it as both an acute and preventive oral CGRP receptor antagonist for adults with migraine.

AbbVie has received European Commission approval for AQUIPTA, or atogepant, as an acute treatment for migraine in adults with or without aura.

The approval expands the product's role in Europe beyond migraine prevention, giving clinicians an oral CGRP receptor antagonist that can be used both as needed for acute migraine attacks and once daily for prevention in adults with chronic or episodic migraine who experience at least four migraine days per month.

Migraine remains a major neurological and socioeconomic burden, affecting daily functioning, productivity and quality of life. AbbVie cited analysis across six European countries showing migraine-related economic burden equivalent to 1.2 to 2.0 percent of GDP, driven by lost productivity from paid and unpaid work.

The approval was supported by the Phase 3 ECLIPSE study, which enrolled 1,328 adults with migraine across 149 sites in Europe, the United Kingdom, Japan, China, South Korea and Taiwan. AQUIPTA met its primary endpoint by achieving statistically significant pain freedom at two hours after treatment of the first migraine attack versus placebo.

The study also showed benefit across secondary endpoints, including freedom from the most bothersome symptom, pain relief at two hours, reduced rescue-medication use within 24 hours and sustained pain freedom from 2 to 48 hours. The safety profile was generally consistent with its preventive migraine indication.