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Lilly's Migraine drug receives FDA approval

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The approval of REYVOW is significant because it represents the first new class of acute migraine treatment approved by the FDA in more than two decades



Eli Lilly and Company has announced that the U.S. Food and Drug Administration (FDA) has approved REYVOW™ (lasmiditan) an oral medication for the acute treatment of migraine, with or without aura, in adults. REYVOW has a unique mechanism of action and is the first and only FDA-approved medicine in a new class of acute treatment for migraine (serotonin (5-HT)1F receptor agonists).

"Millions of people with migraine face an ongoing battle with the unresolved pain and symptoms of a migraine attack. There is a substantial unmet need for new acute treatments for migraine, like REYVOW, which is why we are proud of today's approval and Lilly's continuing contribution to the migraine community," said Gudarz Davar, M.D., vice president, neurology development, Lilly Bio-Medicines. "New expectations have been set in migraine care; pain freedom is now the treatment goal for people living with migraine and those who treat them. At Lilly, we are pioneering innovative medicines to provide new options for patients with migraine."

As with other medicines with central nervous system (CNS) activity, the FDA required abuse potential studies for REYVOW. Abuse potential refers to the likelihood that abuse will occur with a particular drug product or substance with CNS activity. Consistent with the FDA's guidance, Lilly conducted a human abuse potential assessment; as part of that assessment, therapeutic doses of REYVOW were associated with less drug liking when compared to alprazolam, but more than placebo.

The recommended controlled substance classification for REYVOW is currently under review by the Drug Enforcement Administration (DEA) and is expected within 90 days of today's FDA approval, after which REYVOW will be available to patients in retail pharmacies.

The New Drug Application (NDA) for REYVOW included data from two Phase 3 single-attack studies (SAMURAI and SPARTAN), which evaluated the safety and efficacy of REYVOW for the acute treatment of migraine in adults.

"For over 25 years, Lilly has been committed to helping people affected by disabling headache disorders, investigating more than a dozen different compounds," said Patrik Jonsson, senior vice president and president, Lilly Bio-Medicines. "The approval of REYVOW is an exciting development for patients and physicians seeking the potential for pain freedom when a migraine attack happens."