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FDA approves Eli Lilly's migraine treatment

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REYVOW has a unique mechanism of action and is the first and only FDA-approved medicine in a new class ofacute treatment for migraine

Eli Lilly and Company has announced that USFDA 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).

Gudarz Davar, M.D., vice president, neurology development, Lilly Bio-Medicines said, "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. 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.

Jan Brandes, M.D., MS, FAAN, assistant clinical professor, Department of Neurology, Vanderbilt University said, "As a physician who specializes in the treatment of migraine and headache disorders, I commonly treat patients who are looking for acute treatment options that offer the chance for pain freedom during migraine attacks. This approval is especially significant because migraine pain is so often severe and incapacitating. With new science comes new hope. Considering up to 40% of people with migraine do not get adequate responses from their initial acute treatment prescription, having a new and novel option like REYVOW is an important development for physicians and the patients we treat."

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

REYVOW is a new oral treatment that binds to 5-HT1F receptors with high affinity and is approved by the FDA for the acute treatment of migraine, with or without aura, in adults. Its therapeutic effects are presumably mediated by agonist effects at this receptor; however, the precise mechanism is unknown.