Reyvow™ (lasmiditan) – New drug approval

- On October 11, 2019, the FDA announced the approval of Eli Lilly's Reyvow (lasmiditan), for the acute treatment of migraine with or without aura in adults.
    - Reyvow is not indicated for the preventive treatment of migraine.
- Migraine headache pain is often described as an intense throbbing or pulsing 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.
    - Migraine is three times more common in women than in men and affects more than 10% of people worldwide.
- Reyvow is a first-in-class serotonin (5-HT) 1F receptor agonist. Reyvow presumably exerts its therapeutic effects in the treatment of migraine through agonist effects at the 5-HT_{1F} receptor; however, the precise mechanism is unknown.
- The efficacy of Reyvow was established in two randomized, double-blind, placebo-controlled studies in 5,236 patients with a history of migraine. Study 1 randomized patients to Reyvow 100 mg, or 200 mg, or placebo and study 2 randomized patients to Reyvow 50 mg, 100 mg, or 200 mg, or placebo. The primary efficacy analyses were conducted in patients that treated a migraine with moderate to severe pain within 4 hours of the onset of the attack. The efficacy of Reyvow was established by an effect on pain freedom at 2 hours and Most Bothersome Symptom (MBS) freedom at 2 hours compared to placebo.
    - In both studies, the percentage of patients achieving pain freedom and MBS freedom 2 hours after treatment was significantly greater among patients receiving Reyvow at all doses compared to those receiving placebo.
    - The percentage of patients achieving pain freedom at 2 hours ranged from 28.3% to 38.8% with Reyvow vs. 15.3% to 21.0% with placebo.
    - The percentage of patients achieving MBS freedom at 2 hours ranged from 40.7% to 48.7% with Reyvow vs. 29.6% to 33.2% with placebo.
- Warnings and precautions for Reyvow include driving impairment, central nervous system depression, serotonin syndrome, and medication overuse headache.
- The most common adverse reactions (≥ 5% and > placebo) with Reyvow use were dizziness, fatigue, paresthesia, and sedation.
- The recommended dose of Reyvow is 50 mg, 100 mg, or 200 mg taken orally, as needed. No more than one dose should be taken in 24 hours, and Reyvow should not be taken unless the patient can wait at least 8 hours between dosing and driving or operating machinery.
    - A second dose of Reyvow has not been shown to be effective for the same migraine attack.
    - The safety of treating an average of more than 4 migraine attacks in a 30-day period has not been established.
- The recommended controlled substance classification for Reyvow is currently under review by the Drug Enforcement Administration (DEA) and is expected within 90 days of FDA approval.

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- Eli Lilly plans to launch Reyvow following the review from the DEA. Reyvow will be available as 50 mg and 100 mg tablets.