Dayvigo™ (lemborexant) – New drug approval

- On December 20, 2019, Eisai announced the FDA approval of Dayvigo (lemborexant), for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

- Dayvigo is an orexin receptor antagonist. In individuals with normal daily sleep-wake rhythms, orexin signaling is believed to promote periods of wakefulness. In individuals with sleep-wake disorders, it is possible that orexin signaling that regulates wakefulness is not functioning normally.

- The efficacy of Dayvigo was established in two randomized, double-blind studies in 1,977 patients with insomnia characterized by difficulties with sleep onset and/or sleep maintenance. Study 1 was a 6-month trial and patients were randomized to placebo, Dayvigo 5 mg, or Dayvigo 10 mg once nightly. The primary efficacy endpoint was the mean change from baseline to end of treatment at 6 months for log-transformed patient-reported sleep onset latency, defined as the estimated minutes from the time that the patient attempted to sleep until sleep onset.

    — Both Dayvigo 5 mg and 10 mg provided a statistically significant improvement vs. placebo for the primary endpoint with a treatment effect of 0.7 (95% CI: 0.6, 0.8).

- Study 2 was a 1-month trial and patients were randomized to placebo, Dayvigo 5 mg or 10 mg, or active comparator once nightly. The primary efficacy endpoint was the mean change in log-transformed latency to persistent sleep from baseline to end of treatment (days 29/30), as measured by overnight polysomnography monitoring.

    — Both Dayvigo 5 mg and 10 mg provided a statistically significant improvement vs. placebo for the primary endpoint. The treatment effect was 0.8 (95% CI: 0.7, 0.9) for Dayvigo 5 mg and 0.7 (95% CI: 0.6, 0.8) for Dayvigo 10 mg.

- Dayvigo is contraindicated in patients with narcolepsy.

- Warnings and precautions for Dayvigo include central nervous system depressant effects and daytime impairment; sleep paralysis, hypnagogic/hypnopompic hallucinations, and cataplexy-like symptoms; complex sleep behaviors; patients with compromised respiratory function; worsening of depression/suicidal ideation; and need to evaluate for co-morbid diagnoses.

- The most common adverse reaction (≥ 5% and at least twice the rate of placebo) with Dayvigo use was somnolence.

- The recommended dose of Dayvigo is 5 mg taken orally no more than once per night, immediately before going to bed, with at least 7 hours remaining before the planned time of awakening.

    — The dose may be increased to the maximum recommended dose of 10 mg based on clinical response and tolerability.

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- Eisai plans to launch Dayvigo following scheduling by the DEA, which is expected to occur within 90 days. Dayvigo will be available as 5 mg and 10 mg tablets.