Quviviq™ (daridorexant) – New drug approval

- On January 10, 2022, Idorsia announced the FDA approval of Quviviq (daridorexant), for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.
    - The FDA has recommended that Quviviq be classified as a controlled substance. The Drug Enforcement Administration (DEA) will assign the scheduling.
- Insomnia is the most common sleep disorder, affecting more than 25 million adults in the U.S.
- Quviviq is a dual orexin receptor antagonist, which blocks the binding of the wake-promoting neuropeptides orexins and is thought to turn down overactive wakefulness.
- The efficacy of Quviviq was evaluated in two randomized, double-blind, placebo-controlled, parallel-group studies. A total of 1,854 patients with insomnia were randomized to receive Quviviq or placebo once daily, in the evening, for 3 months. Primary efficacy endpoints for both studies were the change from baseline to month 1 and month 3 in Latency to Persistent Sleep (LPS) and Wake After Sleep Onset (WASO). LPS is a measure of sleep induction and WASO is a measure of sleep maintenance.
    - In study 1, doses of 25 and 50 mg Quviviq showed a statistically significant improvement vs. placebo on LPS and WASO at month 1 and month 3.
    - In study 2, Quviviq 25 mg showed a statistically significant improvement vs. placebo on WASO at month 1 and month 3.
- Quviviq is contraindicated in patients with narcolepsy
- Warnings and precautions for Quviviq include central nervous system-depressant effects and daytime impairment; worsening of depression/suicidal ideation; sleep paralysis, hypnagogic/hypnopompic hallucinations, and cataplexy-like symptoms; complex sleep behaviors; patients with compromised respiratory function; and need to evaluate for co-morbid diagnoses.
- The most common adverse reactions (≥ 5% of patients treated with Quviviq and at an incidence ≥ than placebo) with Quviviq use were headache, somnolence or fatigue.
- The recommended dosage range of Quviviq is 25 mg to 50 mg taken orally no more than once per night within 30 minutes of going to bed (with at least 7 hours remaining prior to planned awakening).
- Idorsia plans to launch Quviviq in May 2022 after controlled substance scheduling by the DEA. Quviviq will be available as 25 mg and 50 mg tablets.