Qelbree® (viloxazine) – Expanded indication

- On April 29, 2022, Supernus Pharmaceuticals announced the FDA approval of Qelbree (viloxazine), for the treatment of attention-deficit hyperactivity disorder (ADHD) *in adults and pediatric patients 6 years and older*.
    - Qelbree was previously approved for this indication in *pediatric patients 6 to 17 years of age*. It is now also approved for adult patients.
- The approval of Qelbree for the expanded indication was based on a randomized, double-blind, placebo-controlled monotherapy study in 374 adults 18 to 65 years of age with ADHD. The primary endpoint was the change from baseline to the end of study on the total score on the ADHD Investigator Symptom Rating Scale (AISRS), an 18-item scale corresponding to 18 symptoms of ADHD. Higher AISRS scores reflect more severe symptoms.
    - The change from baseline in the AISRS total score was -15.5 with Qelbree vs. -11.7 with placebo (difference -3.7, 95% CI: -6.2, -1.2).
- Qelbree carries a boxed warning for suicidal thoughts and behaviors.
- The most common adverse events (≥ 5% and at least twice the rate of placebo) with Qelbree use in adults were insomnia, headache, somnolence, fatigue, nausea, decreased appetite, dry mouth and constipation.
- The recommended starting dosage of Qelbree for adults is 200 mg orally once daily. Dosage may be titrated in increments of 200 mg weekly to the maximum recommended dosage of 600 mg once daily, depending on response and tolerability.
    - Refer to the Qelbree drug label for pediatric dosing.