Qelbree™ (viloxazine) – New drug approval

- On April 2, 2021, Supernus Pharmaceuticals announced the FDA approval of Qelbree (viloxazine), for the treatment of attention-deficit hyperactivity disorder (ADHD) in pediatric patients 6 to 17 years of age.

- Qelbree is a selective norepinephrine reuptake inhibitor. Qelbree is not a controlled substance.

- The efficacy of Qelbree was established in three randomized, double-blind, three-arm, placebo-controlled studies in patients with ADHD. Study 1 randomized 477 patients aged 6 to 11 years to Qelbree 100 mg or Qelbree 200 mg or placebo. Study 2 randomized 313 patients aged 6 to 11 years to Qelbree 200 mg or Qelbree 400 mg or placebo. Study 3 randomized 310 patients aged 12 to 17 years to Qelbree 200 mg or Qelbree 400 mg or placebo. The primary endpoint for all three trials was the change from baseline in the total ADHD Rating Scale score (ADHD-RS-5). A decrease in ADHD-RS-5 scores from baseline indicates clinical improvement.

    - Across all three clinical trials, there was a statistically significant mean change (reduction) from baseline for ADHD-RS-5 in patients treated with Qelbree compared to placebo. The placebo-subtracted difference for Qelbree 200 mg compared to placebo was -6.9 (95% CI: -10.0, -3.8), -6.0 (95% CI: -10.0, -1.9) and -4.5 (95% CI: -8.4, -0.6), for Studies 1, 2 and 3, respectively.
    - Results were similar for the Qelbree 100 and 400 mg doses vs. placebo.

- Supernus Pharmaceuticals plans to submit a supplemental New Drug Application to the FDA for Qelbree use for adults in the second half of 2021.

- Qelbree carries a boxed warning for suicidal thoughts and behaviors.

- Qelbree is contraindicated in patients:

    - Receiving concomitant treatment with monoamine oxidase inhibitors (MAOIs) or within 14 days after discontinuation of treatment with an MAOI.
    - Receiving concomitant treatment with sensitive CYP1A2 substrates or CYP1A2 substrates with a narrow therapeutic range.

- Additional warnings and precautions for Qelbree include blood pressure and heart rate increases; activation of mania or hypomania; and somnolence and fatigue.

- The most common adverse reactions (≥ 5% and twice the rate of placebo) with Qelbree use were somnolence, decreased appetite, fatigue, nausea, vomiting, insomnia, and irritability.

- The recommended starting dose of Qelbree in pediatric patients 6 to 11 years of age is 100 mg orally once daily. The dosage may be titrated in increments of 100 mg at weekly intervals to the maximum recommended dosage of 400 mg once daily, depending on response and tolerability.

- The recommended starting dose of Qelbree in pediatric patients 12 to 17 years of age is 200 mg orally once daily. After 1 week, dosage may be titrated by an increment of 200 mg to the maximum recommended dosage of 400 mg once daily, depending on response and tolerability.

- Qelbree capsules should be swallowed whole or the capsules can be opened and the entire contents sprinkled over a teaspoonful of applesauce.

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- Supernus Pharmaceutical plans to launch Qelbree in the second quarter of 2021. Qelbree will be available as 100 mg, 150 mg, and 200 mg extended-release capsules