PATIENT CASE

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INDICATION

Qelbree is indicated for the treatment of ADHD in adults and pediatric patients 6 years and older.

IMPORTANT SAFETY INFORMATION

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

In clinical studies, higher rates of suicidal thoughts and behaviors were reported in patients with ADHD treated with Qelbree than in patients treated with placebo. Closely monitor all Qelbree-treated patients for clinical worsening and for emergence of suicidal thoughts and behaviors.

Please see full Important Safety Information on page 2.

ONCE-DAILY Qelbree® viloxazine extended-release capsules 100 mg 150 mg 200 mg

SARAH, 9 YEARS OLD

Patient portrayal.

Individual results may vary.

Current ADHD treatment[1]: None—recently tried a 3-month holistic approach after discontinuing stimulant treatment.

STUDY 1 (P301)[2]:
Randomized, double-blind, placebo-controlled, fixed-dose, parallel-group, multicenter study of children 6 to 11 years of age with ADHD, with a baseline ADHD-RS-5 total score ≥28, CGI-S ≥4. The primary endpoint was CFB in the ADHD-RS-5 total score at EOS. **Results:** Total score at EOS was significantly reduced with Qelbree vs placebo. The CFB in ADHD-RS-5 total score at EOS (LS mean ± SE) was -16.6±1.16 for Qelbree 100 mg/day, -17.7±1.12 for Qelbree 200 mg/day, and -10.9±1.14 for placebo.

OLE (P310)[2]:
Patients who completed a previous double-blind study of Qelbree for the treatment of ADHD were eligible to enroll in an open-label safety trial. Patients 6 to 11 years of age were initially treated at 100 mg/day, and dose could be adjusted by 100 mg/week to a range of 100 mg to 400 mg/day, based on clinical response.

STUDY 1: Primary analysis is based on mITT population; EOS=Week 6.[1]

OLE 310: Analysis populations: all subjects who have documented informed consent and have taken at least 1 dose of Qelbree during the OLE were in the safety population.[2]

CLINICAL CONSIDERATIONS[1]:

Inattention and hyperactivity were causing significant impairment in school and at home

- Evaluation was scheduled after caregiver learned that Sarah would have to repeat the 3rd grade

SARAH'S THERAPEUTIC HISTORY[1]:

- ADHD symptoms since kindergarten
- Pediatrician prescribed a stimulant, which helped "a little bit" but changed Sarah's personality
- Holistic approach was tried for 3 months but was ineffective

SARAH'S NEED FOR SYMPTOM IMPROVEMENT[1]:

ADHD-RS-5 score at first visit was 41 (Markedly ill)

- Marked impairment on the CGI-S
- Tolerability concerns made therapy with another stimulant inappropriate

CLINICAL TREATMENT WITH QELBREE[1]:

- Sarah completed the 6-week double-blind study (Study 1/P301) where she received Qelbree 200 mg/day*
  - Sarah's EOS ADHD-RS-5 total score was 23
- Sarah then entered the open-label treatment study (OLE/P310) where she was started on Qelbree 100 mg/day
  - Her dose was gradually titrated to 400 mg per day, and her total ADHD-RS-5 score remained similar to the score she experienced in Study 1 (P301)
  - CGI-I of "much improved"
- An adverse event required a dose adjustment
  - Sarah's Qelbree dose was decreased to 300 mg/day and she continued to show response to once-daily Qelbree

*During the clinical trial, Sarah, her parents, and her treatment team were blinded to dose.

Abbreviations: ADHD, attention-deficit/hyperactivity disorder; ADHD-RS-5, Attention-Deficit/Hyperactivity Disorder Rating Scale, 5th Edition; CFB, change from baseline; CGI-I, Clinical Global Impression-Improvement; CGI-S, Clinical Global Impression-Severity of Illness; EOS, end of study; LS mean, least-squares mean; mITT, modified intent to treat; SE, standard error.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- Concomitant administration of a monoamine oxidase inhibitor (MAOI), or dosing within 14 days after discontinuing an MAOI, because of an increased risk of hypertensive crisis
- Concomitant administration of sensitive CYP1A2 substrates or CYP1A2 substrates with a narrow therapeutic range

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WARNINGS & PRECAUTIONS

- *Suicidal thoughts and behaviors*: Closely monitor all Qelbree-treated patients for clinical worsening and emergence of suicidal thoughts and behaviors, especially during the initial few months of drug therapy, and at times of dosage changes
- *Heart rate, blood pressure increases*: Qelbree can cause an increase in diastolic blood pressure and heart rate. Assess these measures prior to starting therapy, following increases in dosage, and periodically during therapy
- *Activation of mania or hypomania*: Noradrenergic drugs may induce a manic or mixed episode in patients with bipolar disorder. Prior to initiating treatment with Qelbree, screen patients to determine if they are at risk for bipolar disorder. Screening should include a detailed psychiatric history, including a personal or family history of suicide, bipolar disorder, and depression
- *Somnolence and fatigue*: Patients should not perform activities requiring mental alertness, such as operating a motor vehicle or hazardous machinery, due to potential somnolence (including sedation or lethargy) and fatigue, until they know how they will be affected by Qelbree

ADVERSE REACTIONS

The most common adverse reactions (≥5% and at least twice the rate of placebo for any dose) in patients 6 to 17 years were somnolence, decreased appetite, fatigue, nausea, vomiting, insomnia, and irritability, and in adults, insomnia, headache, somnolence, fatigue, nausea, decreased appetite, dry mouth, and constipation.

PREGNANCY

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Qelbree during pregnancy. Healthcare providers are encouraged to register patients by calling the National Pregnancy Registry for Psychiatric Medications at 1-866-961-2388 or by visiting www.womensmentalhealth.org/preg.

REFERENCES: 1. Data on file, Supernus Pharmaceuticals, Inc. **2.** Qelbree [package insert]. Rockville, MD: Supernus Pharmaceuticals, Inc.

Please see full Prescribing Information, including Boxed Warning.

Supernus® Pharmaceuticals