Qelbree® is the first novel, nonstimulant treatment option for adults with attention-deficit/hyperactivity disorder (ADHD) in 20 years.

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.

Important Safety Information below

Qelbree® Approval Details

- Qelbree® is indicated for the treatment of ADHD in adults and pediatric patients 6 years and older.
- On April 29, 2022 the FDA approved Qelbree for the treatment of ADHD in adults, aged 18 and older.
  - There has not been a nonstimulant for adults with ADHD approved in 20 years.
- Once-daily, rapid and extended release, sprinkleable capsules for full-day exposure.[1,2]
- Qelbree capsules may be taken whole or entire contents can be sprinkled over a spoonful of soft food (pudding or applesauce). Consume the soft food mixture in its entirety, without chewing, within 15 minutes for pudding or within 2 hours for applesauce; do not store for future use. Do not cut, crush, or chew the capsules.
- Proven safety and tolerability, with no evidence of abuse potential observed in clinical studies.[1,2]
- This product may be an appropriate treatment option for millions of US children 6 years and older, adolescents, and adults who have ADHD.[3,4] Up to 90% of those diagnosed with ADHD in childhood continue to have symptoms into adulthood.[5]

How it Works

Qelbree is the first 2-bead Microtrol™ Technology delivery of nonstimulant viloxazine for 24-hour patient exposure.[1,2]

- Qelbree was found to be free of physical drug dependence in 5 animal models of abuse liability.[6]
- No withdrawal symptoms or signs of dependence were reported as adverse events (AE) during human clinical trials.[2]

IMPORTANT SAFETY INFORMATION

- 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

Adult Phase III Trial

Clinical trial was a randomized, double-blind, placebo-controlled, multicenter, parallel-group, flexible-dose study.

Primary endpoint

CFB (Change from Baseline) in the AISRS total score at EOS (End of Study), Qelbree treatment group.

ADULTS

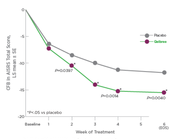
Study P306

Age group: 18 to 65 years of age

ITT population: N=354

Treatment Arms: Flexible dosing for Qelbree 200mg-600mg or placebo

Proven efficacy in treating ADHD at EOS: Inattention and hyperactivity/impulsivitysymptom score reductions observed as early as week 2.[1,2]



No study visit was scheduled/performed at week 5.

Study P306 Results:

- At baseline the mean (± SE) total AISRS score was comparable between groups: 38.5 ± 6.56 for Qelbree and 37.6 ± 6.62 for placebo.
- Total AISRS score at EOS was significantly reduced with Qelbree vs placebo. The CFB in AISRS total score at EOS (LS mean ± SE) was -15.5 ±0.91 for Qelbree and -11.7 ±0.90 for placebo.[1]
- Once-daily Qelbree delivers symptom score reductions on the subscales of both inattention and hyperactivity/impulsivity in adults.[2]
- Once-daily Qelbree demonstrates proven safety and tolerability in clinical studies with no evidence of abuse potential.[1,2]

Pediatric & Adolescent Phase III Trials

All clinical trials were randomized, double-blind, placebo-controlled, 3-arm, parallel-group, multicenter studies.

Primary endpoint

CFB (Change from Baseline) in the ADHD-RS-5 total score at EOS (End of Study), Qelbree treatment group.

CHILDREN

Study P301

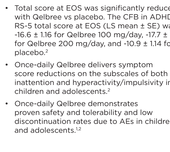
Age group: 6 to 11 years of age

ITT population: N=460

Treatment Arms: 100mg, 200mg or placebo

Primary efficacy measure: CFB to EOS on the ADHD-RS-5 Total Score vs placebo

Proven efficacy in treating ADHD at EOS: Inattention and hyperactivity/impulsivity symptom score reductions observed as early as week 1.[1,2]



Study P301 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.[2]
- Once-daily Qelbree delivers symptom score reductions on the subscales of both inattention and hyperactivity/impulsivity in children and adolescents.[2]
- Once-daily Qelbree demonstrates proven safety and tolerability and low discontinuation rates due to AEs in children and adolescents.[1,2]

ADOLESCENTS

Study P302

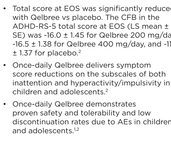
Age group: 12 to 17 years of age

ITT population: N=301

Treatment Arms: 200mg, 400mg or placebo

Primary efficacy measure: CFB to EOS on the ADHD-RS-5 Total Score vs placebo

Proven efficacy in treating ADHD at EOS: Inattention and hyperactivity/impulsivity symptom score reductions observed as early as week 1.[1,2]



Study P302 results:

- Total score at EOS was significantly reduced with Qelbree vs placebo. The CFB in the ADHD-RS-5 total score at EOS (LS mean ± SE) was -16.0 ± 1.45 for Qelbree 200 mg/day, -16.5 ± 1.38 for Qelbree 400 mg/day, and -11.4 ± 1.37 for placebo.[2]
- Once-daily Qelbree delivers symptom score reductions on the subscales of both inattention and hyperactivity/impulsivity in children and adolescents.[2]
- Once-daily Qelbree demonstrates proven safety and tolerability and low discontinuation rates due to AEs in children and adolescents.[1,2]

IMPORTANT SAFETY INFORMATION CONT'D

WARNINGS & PRECAUTIONS

- *Suicidal Thoughts and Behaviors:* Closely monitor all Qelbree-treated patients for clinical worseningand 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.

Please see full Prescribing Information, including Boxed Warning.

References:

1. Qelbree [package insert]. Rockville, MD: Supernus Pharmaceuticals, Inc.
2. Data on file, Supernus Pharmaceuticals.
3. Centers for Disease Control and Prevention (CDC). Attention-deficit/hyperactivity disorder (ADHD)—Data and statistics about ADHD. CDC website. Accessed March 17, 2022. https://www.cdc.gov/ncbddd/adhd/data.html.
4. Castellanos FX, Proal E. Large-scale brain systems in ADHD: beyond the prefrontal-striatal model. Trends Cogn Sci. 2012;16(1):17-26. doi:10.1016/j.tics.2011.11.007
5. Sibley MH, Arnold LE, Swanson JM, et al. Variable Patterns of Remission From ADHD in the Multimodal Treatment Study of ADHD. Am J Psychiatry. 2022;179(2):142-151. doi:10.1176/appi.ajp.2021.21010032
6. Yanagita T, Wakasa Y, Kiyohara H. Drug dependence potential of viloxazine hydrochloride tested in rhesus monkeys. Pharmacol Biochem Behav. 1980;12:155-161.

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