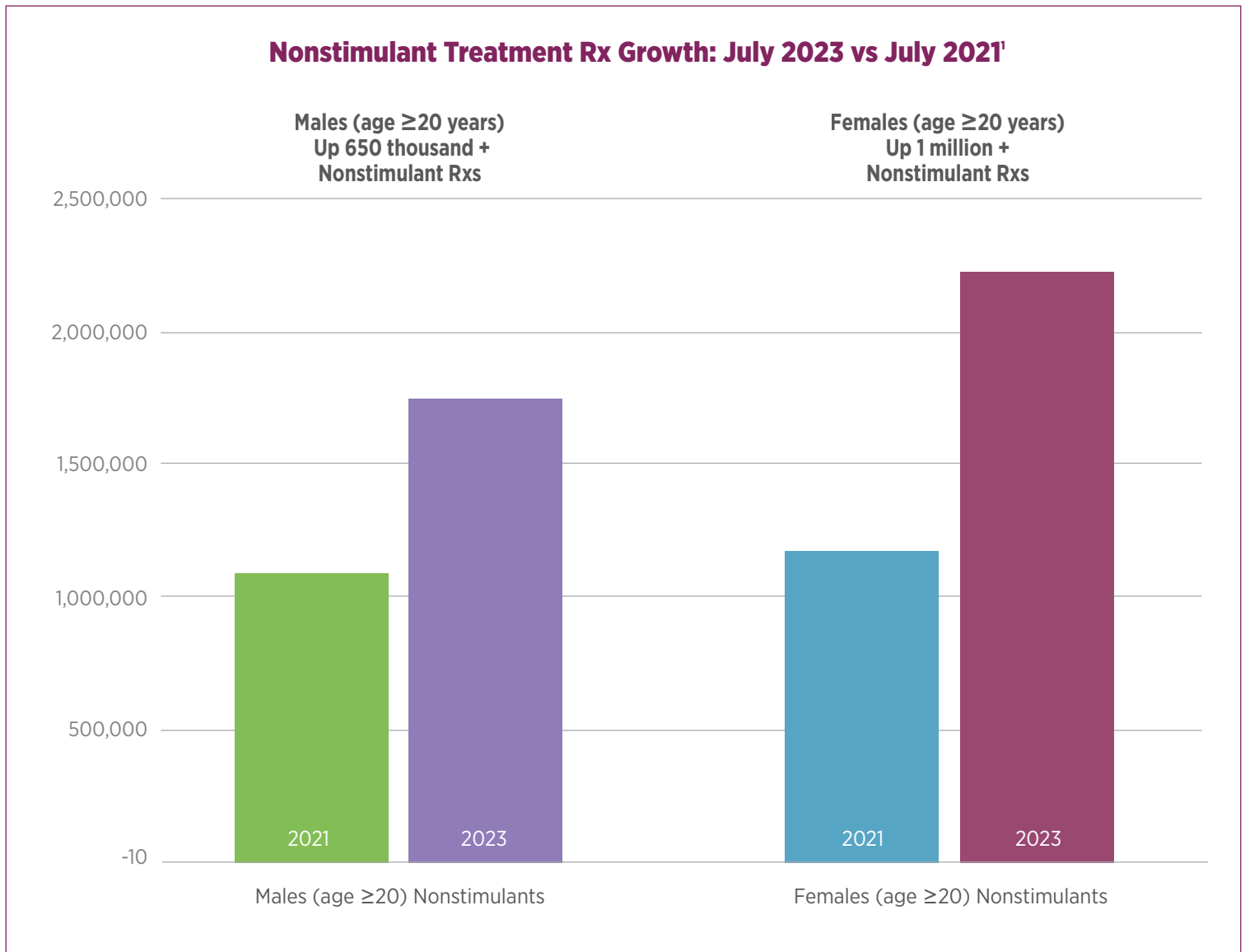


From 2021–2023:

Nonstimulant prescription growth for adult females outpaced stimulant growth by 4.5 times¹

Nonstimulant Rx's increased by over 1 million in adult female ADHD patients¹



More adult patients are being treated with nonstimulants than previous years¹...

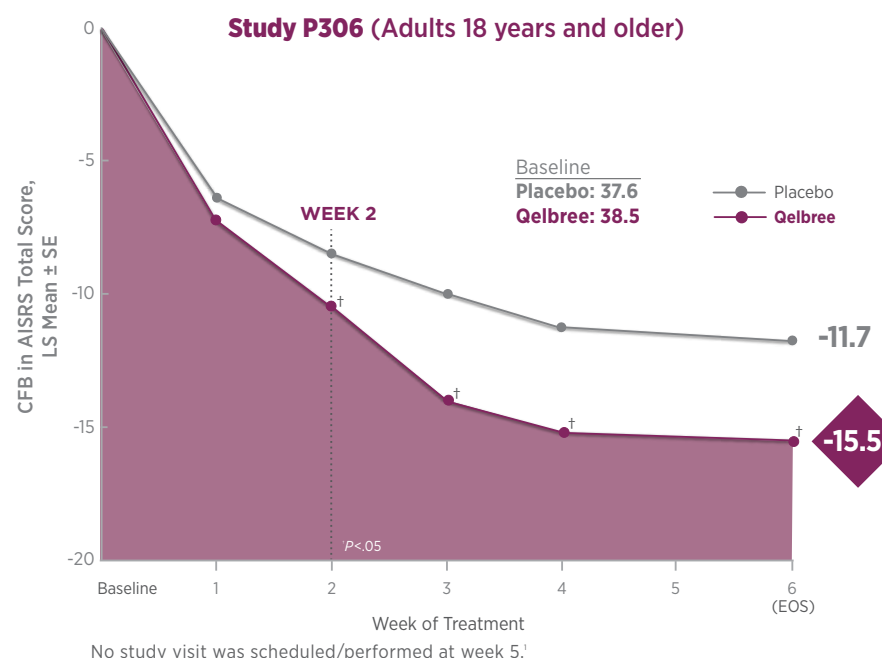
Abbreviations: ADHD, attention-deficit/hyperactivity disorder.

Source: MAT IQVIA NPA Market Dynamics 7/2020 to 7/2023.

A NOVEL, NONSTIMULANT, that works for ADHD^{2,5} in adults 18 years and older

Phase III trial: proven efficacy in treating ADHD at EOS (n=354)²

Inattention and hyperactivity/impulsivity symptom score reductions observed as early as week 2¹



Methodology¹: Randomized, DB, placebo-controlled, multicenter, parallel-group, flexible-dose study of adults 18 to 65 years of age (Study P306). The primary endpoint was CFB at EOS (6 weeks) in AISRS total score with an established ADHD diagnosis (DSM-5) ≥6 months before screening, confirmed with the SCID-5-CT, and an AISRS total score ≥26 at the screening and baseline visits. **Results²:** Total AISRS score at EOS was significantly reduced in adults treated 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.

Study P306 results

At baseline, the AISRS Total Score was comparable between groups: 38.5 for Qelbree and 37.6 for placebo. AISRS Total Score at EOS was significantly reduced with Qelbree vs placebo. The CFB in AISRS Total Score at EOS was -15.5 for Qelbree and -11.7 for placebo.²

Abbreviations: AISRS, ADHD Investigator Symptom Rating Scale; CFB, change from baseline; DB, double blind; DSM-5, *Diagnostic and Statistical Manual of Mental Disorders*, 5th edition; EOS, end of study; LS mean, least-squares mean; MMRM, mixed-model repeated measures; SCID-5-CT, Structured Clinical Interview for DSM-5-Clinical Trials; SE, standard error.

• Once-daily Qelbree delivers significant symptom score reductions on the subscales of both inattention and hyperactivity/impulsivity in adults¹

• Once-daily Qelbree demonstrates proven safety and tolerability with no evidence of abuse potential²⁻⁴

*Branded ADHD products launched in last 5 years (as of September 2022).

INDICATION

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

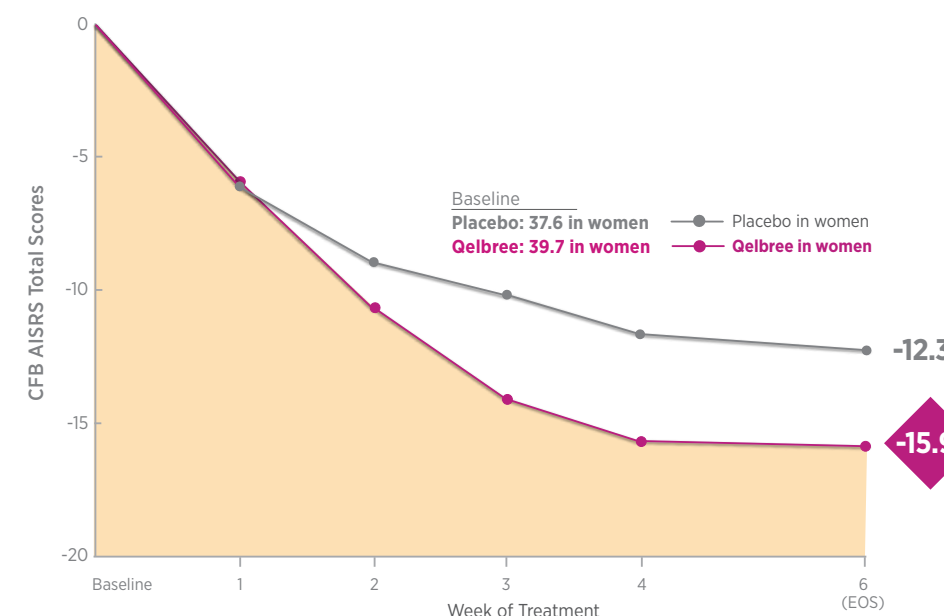
IMPORTANT SAFETY INFORMATION

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 4.

Post hoc analysis: change in AISRS Total Score in women (n=167)¹



Methodology: A post hoc analysis was conducted using Phase 3 trial results (P306) in adults with ADHD.¹

• CFB in the AISRS total score was analyzed in the adult female population using an MMRM approach¹

• This analysis was limited by its post-hoc nature, including lack of an *a priori* power analysis and limited sample size of women. These data are descriptive and conclusions cannot be drawn.¹

Have you discussed Qelbree with your adult female patients with ADHD?



College student



Professional



Stay-at-home mom

All images in this brochure are patient portrayals.

A NOVEL, NONSTIMULANT, that works for ADHD^{2,3} in adults 18 years and older

Long-term safety and efficacy trial of Qelbree in adult patients (n=159)¹

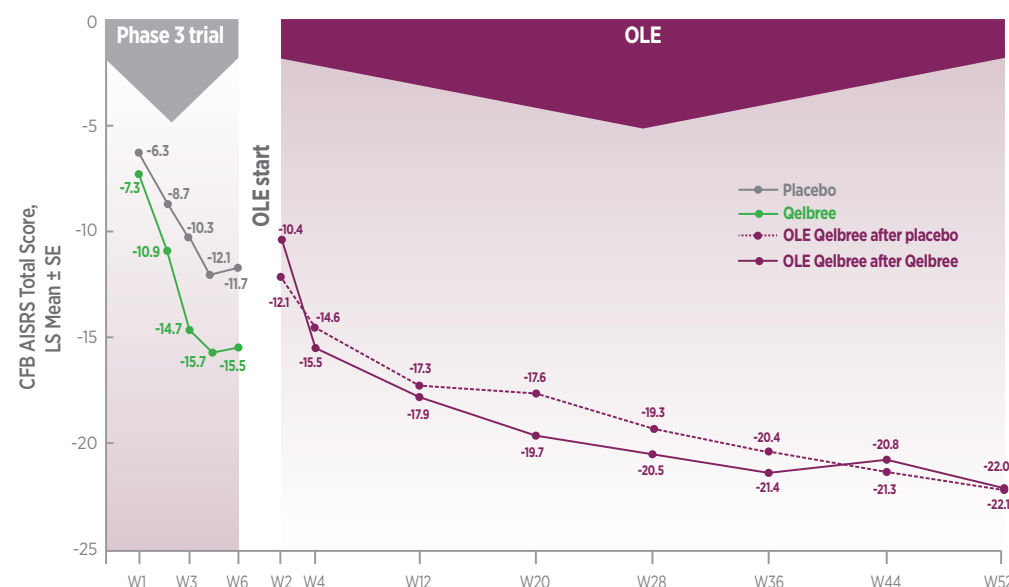
OLE study (P311): Qelbree 200 mg/day to 600 mg/day¹

Methodology: Open-label, long-term, multicenter, flexible dose study of Qelbree in adults diagnosed with ADHD who completed Study P306; the OLE was conducted from January 2020 through July 2022. For patients with a rollover from P306 of <7 days, all efficacy and safety assessments collected at subjects' EOS visit served as their efficacy and safety assessments for visit 1 (P311). For a rollover of >7 days, a screening visit for eligibility was scheduled and visit 1 baseline efficacy and safety were collected. All subjects entering the OLE received Qelbree 200 mg/day during the first 2 weeks of the study. At visit 2/W2, and all subsequent visits, the dose of Qelbree could be titrated up or tapered down in increments of 50 mg/day to 200 mg/day per week to a target dose within the range of 200 mg/day to 600 mg/day, based on subjects' clinical response and tolerability. After week 12, subjects were allowed to use certain approved concomitant ADHD medications (n=9). **Primary objective:** Collect long-term safety data on Qelbree monotherapy in the adult population. **Secondary objective:** Evaluate the efficacy of Qelbree as monotherapy for the treatment of ADHD in the adult population.

Long-term data: AISRS Total Score in the OLE analysis at 12 months¹

Mean change from baseline in AISRS Total Score¹

- The overall mean baseline AISRS Total Score was 37.6 for placebo and 38.5 for Qelbree¹



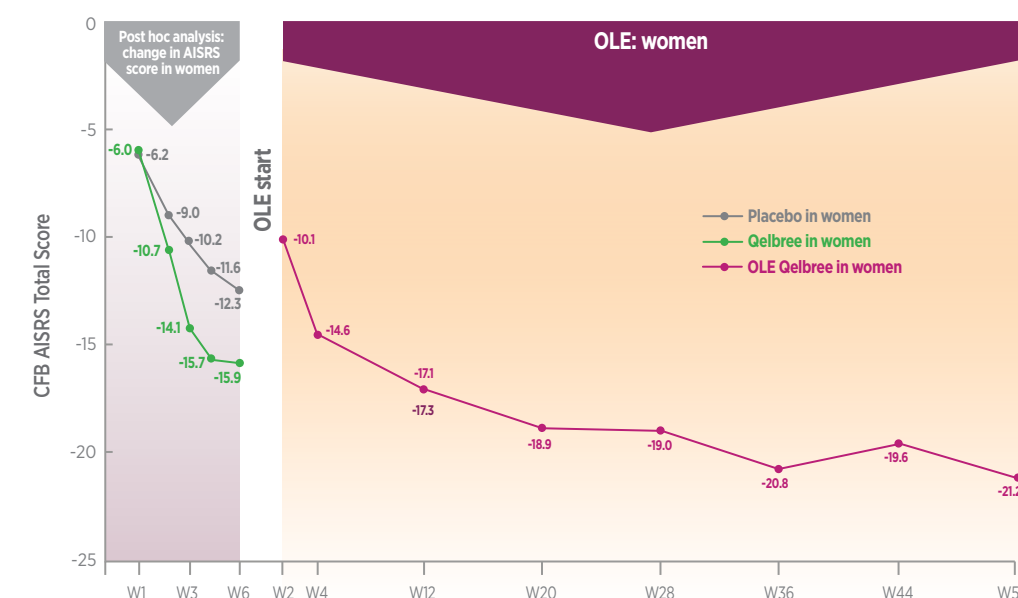
*Branded ADHD products launched in last 5 years (as of September 2022).

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

Post hoc analysis: long-term (OLE) data on women with ADHD treated with Qelbree—AISRS Total Score at 12 months¹

Mean change from baseline in AISRS Total Score in women¹



Methodology: A post hoc analysis was conducted using OLE trial data (P311) in adults with ADHD.¹

- CFB in the AISRS Total Score was analyzed in the adult female population using MMRM approach¹

- Data from patients in the OLE trial and this post-hoc analysis is descriptive only; there are no statistics or a placebo group from which to draw a comparison of long-term safety or efficacy¹
- Enrollment in the OLE safety trial was temporarily closed due to COVID-19 pandemic restrictions; therefore some subjects did not roll over into the OLE immediately after the DB week 6 (EOS) visit¹

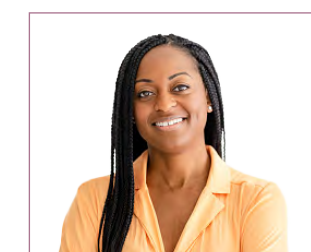
Have you discussed Qelbree with your adult female patients with ADHD?



Blogger



Recent grad



Business owner

Abbreviations: COVID-19, novel coronavirus 19; OLE, open-label extension; W, week.

Please see full [Important Safety Information](#) on page 4.

INDICATION

Qelbree® (viloxazine extended-release capsules) 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.

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

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 ($\geq 5\%$ 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. 2. Qelbree [package insert]. Rockville, MD: Supernus Pharmaceuticals, Inc. 3. Yanagita T, Wakasa Y, Kiyohara H. Drug dependence potential of viloxazine hydrochloride tested in rhesus monkeys. *Pharmacol Biochem Behav*. 1980;12:155-161. 4. Food and Drug Administration. Table of Prescription Stimulant Label Changes. May 10, 2023. Accessed July 13, 2023. <https://www.fda.gov/media/168050/downloads> 5. Food and Drug Administration. Novel drug approvals for 2021. May 13, 2022. Accessed January 7, 2023. <https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2021>.

Please see accompanying full [Prescribing Information](#), including Boxed Warning.



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