lead to appropriate referral and follow-up with primary care or women's clinic providers.

Ongoing efforts will be put forth to increase group attendance, to incorporate participation from unit staff, and to build this group into a resident curriculum for group therapy.

**Funding.** No Funding

# Effects of Viloxazine ER (Qelbree®) on Weight and Height Trajectories: Interim Results From a Long-term, Open-Label Extension Trial in Pediatric ADHD

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**Abstract**

**Introduction.** Stimulant medications and the norepinephrine reuptake inhibitor, atomoxetine, contain warnings regarding potential for slowing of growth (weight and height) in children and recommend monitoring of growth when using these medications for pediatric ADHD. Viloxazine ER (viloxazine extended-release capsules; Qelbree®), is a nonstimulant medication, FDA-approved for ADHD in adults and children (≥6 years of age). Viloxazine ER has pharmacologic differences from other approved ADHD medications and might not affect growth in the same manner as other therapies. A safety analysis was conducted to determine viloxazine ER effects on growth and weight trajectories in pediatric ADHD patients with long-term use.

**Methods.** Data were evaluated from five DBPC, phase 2 and 3 clinical trials and an ongoing long-term, open-label extension (OLE) trial (NCT02736656). Viloxazine ER doses during the trials ranged from 100–400 mg/day (age 6–11 yrs) or 100–600 mg/day (age 12–17 yrs). Height and weight were evaluated pre-treatment in both DB and OLE every 3 months during the OLE, and converted into percentile values and corresponding z-scores using Centers for Disease Control (CDC) normal growth curves to evaluate growth trajectories. The incidence of weight- and growth-related adverse events (AEs) terms were also evaluated.

**Results.** At the time of data cut (31 July 2019), 1097 subjects had received at least one dose of viloxazine ER in the OLE (66% male, mean (SD) age 10.8 (3.06), 59% age 6–11, mean (SD) BMI 18.8 (3.42) kg/m$^2$, height 146.7 (17.46) cm, weight 42.1 (16.01) kg. During the OLE, mean (SE) z-scores for height and weight were between -1 and 1 for all timepoints, indicating growth measures within a normal range compared with expected values. Similar results were observed when weight and height were analyzed by sex and by age categories. Growth data were available for 338 subjects at 12 months. Among these subjects, the mean (SD) change from baseline in weight-for-age z-score was -0.2 (0.5) and height-for-age z-score was -0.14 (1.1). Adverse events relevant to weight and growth in the DB trials (incidence ≥ 1%) included (viloxazine ER [100–600 mg/day] n=1117 vs. placebo n=487): decreased appetite (8.1% vs. 0.8%), nausea (5.1% vs. 2.7%), vomiting (4.7% vs. 1.4%), weight increase (0.4% vs. 1.2%) and weight decrease (1.3% vs. 0.4%), and increased appetite (0.2% vs. 1.2%). During the OLE weight-and growth-related AEs reported for ≥ 1% of subjects were: decreased appetite 5.8%, vomiting 2.7%, nausea 2.4%, weight decreased 2.3%, and weight increased 2.0%.

**Conclusions.** Over time, pediatric subjects taking viloxazine ER, on average, maintained normal weight and height relative to the CDC's child growth charts. However, because Qelbree may affect weight, it is recommended that healthcare providers check patient weight before starting and while using viloxazine ER.

**Funding.** Supernus Pharmaceuticals, Inc.

# Impact of Viloxazine Extended-Release Capsules (Qelbree®) on Executive Function in Adults With ADHD During an Open-Label Extension Study

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**Abstract**

**Introduction.** Executive function deficits (EFDs) are associated with attention-deficit/hyperactivity disorder (ADHD). Viloxazine ER (viloxazine extended-release capsules; Qelbree®) is a novel, nonstimulant, FDA-approved treatment for ADHD in persons ≥6 years of age. In a Phase 3, double-blind (DB), placebo-controlled trial in adults (NCT04016779), viloxazine ER-treated subjects exhibited significant improvement in both ADHD core symptoms (inattention and hyperactivity/impulsivity) compared to placebo. In addition, improvement in EFDs was observed in subjects using the Behavior Rating Inventory of Executive Function – Adult Version (BRIEF-A, Self-report), a 75-item scale that assesses aspects of executive function (Metacognition Index [MI]) and problems with self-regulation (Behavioral Regulation Index [BRI]) and overall functioning (Global Executive Composite [GEC]). At Week 6 in DB trial, a statistically significant greater reduction (improvement) was observed in viloxazine ER-treated subjects compared to placebo in the GEC and MI, but not in the BRI. Here, preliminary results of further BRIEF-A assessments in adults during an ongoing open-label extension (OLE) safety trial (NCT04143217) are presented.

**Methods.** Subjects complete the BRIEF-A at baseline and at Week 6 in the DB trial, and at Week 4 and every 8 weeks thereafter in the OLE trial. Subjects rate each BRIEF-A item on a 3-point scale (1=Never, 2=Sometimes, or 3=Often) based on the last month.

https://doi.org/10.1017/S1092852923001323 Published online by Cambridge University Press