12 per Clinical Global Impression of Change (GIC); 23 or 49 (47%) per Patient GIC. Total motor AIMS scores were reduced by 4.8 points at week 12. Among the 39 (78%) patients who responded to the questionnaire, 72% found it easy to understand when/which dosage to take, 77% easy to remember to take their medication, 74% easy to change the dose weekly, 69% easy to follow kit instructions, and 77% easy to use the kit overall.

Conclusions. 78% of patients with TD successfully completed the 4-week titration kit in approximately 4 weeks, with adherence rates of 97.2%. 95% of patients reaching week 12 had a maintenance dosage ≥24 mg/day. 49% of patients achieved treatment success based on Clinical GIC. Patients reported high levels of satisfaction with the titration kit and 77% found it easy to use. The 4-week patient titration kit enabled patients to titrate DTBZ to an optimal dosage and experience effectiveness similar to the pivotal clinical trials.

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Evaluating Viloxazine ER (Qelbree) Administered with Psychostimulants For Pediatric ADHD: Analysis of a Phase 4 Safety Trial

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Introduction. Viloxazine extended-release (ER) is an FDA-approved, nonstimulant medication for pediatric (≥6 years) and adult ADHD. Apart from use as monotherapy, nonstimulants may be combined with stimulants when patients experience inadequate response or difficulties with medication tolerability. This phase IV, open-label trial (NCT04786990) evaluated the safety and tolerability of viloxazine ER administration with psychostimulants in children and adolescents with ADHD. Differences between morning and evening use of viloxazine ER were also assessed.

Methods. Children and adolescents (6 – 17 years) experiencing inadequate response (ADHDRS-5 ≥24 and CGI-S ≥3) to psychostimulant treatment (methylphenidate or amphetamine) were enrolled. Subjects maintained stable stimulant use throughout the trial. Following an up to 4-week screening period, subjects continuing to show inadequate response received flexibly dosed viloxazine ER (100-400 mg/day children; 200-600 mg/day adolescents) each morning during Weeks 1-4 and each evening during Weeks 5-8. Safety, tolerability, and efficacy were assessed relative to Baseline, and for change from baseline for morning vs. evening dosing.

Results. 56 subjects received viloxazine ER with 85.7% of these completing the study. Adverse events were reported by 55.4% of subjects, most commonly headache (17.9%), decreased appetite (12.5%), and upper respiratory tract infection (10.7%); onset was more common during AM dosing trial weeks [50% of subjects reported AEs during Weeks 1-4 and 36% during Weeks 5-8]. AEs were largely mild (32.1%) or moderate (21.4%) and led to discontinuation for 2 (3.6%) subjects. Baseline mean (SD) Investigator Rated-ADHD-Rating Scale 5th ed. (IR-ADHD-RS-5) score was 37.2 (8.35), n=56. Significant improvement in IR-ADHD-RS-5 was seen by Week 1[-6.9 (8.16), n=56; P<.0001)] and continued through Weeks 4 and 8 [-13.5 (9.70) p<.0001 and -18.2 (9.99) p<.0001, respectively]. Over 50% of subjects were rated much or very much improved on CGI-I at endpoint. Scores on the sleep disturbance Scale for Children (SDSC) scale also improved at both Weeks 4 and 8 [-8.8 (14.03) P<.0001 and -10.3(17.39) P=.0002, respectively], as did Parent-ratings of morning and evening ADHD symptoms and behavior, suggesting that morning and evening administration of viloxazine ER were both efficacious.

Conclusions. Viloxazine ER showed acceptable safety and tolerability when administered with stimulant medications in this Phase IV open-label trial. Administration of viloxazine ER in the evening instead of the morning did not appear to affect safety, nor the trajectory of drug response or sleep improvement.

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Qelbree (viloxazine extended-release capsules): Final Results of the Long-Term, Phase 3, Open-Label Extension Trial in Adults with ADHD

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Introduction. Viloxazine extended-release (ER) is an FDA-approved nonstimulant medication for ADHD in children (≥6 years) and adults. Approval in adults was based on a double-blind (DB) pivotal trial [NCT04016779] showing statistically significant efficacy on the Adult ADHD Investigator Symptom Rating Scale (AISRS; primary outcome). Here we report final results from the long-term, open-label extension (OLE) safety trial [NCT04143217] conducted as a following to the DB trial.

Methods. Upon completing DB treatment, consenting subjects who enrolled in the OLE received viloxazine ER 200 mg/day, with flexible titration to an optimal maintenance dose (200-600 mg/day). Addition of a stimulant was permitted, at investigator's discretion, following Week 12. OLE trial enrollment was

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