Abst

Objective: To evaluate the effect of augmentation therapy with lisdexamfetamine dimesylate (LDX) in adults with major depressive disorder (MDD) who were continuing open-label escitalopram treatment.

Methods

Participants: 44 of 173 randomized participants with residual symptoms, based on HAM-D17 scores, were considered eligible for augmentation. Participants had a mean (SD) age of 45 (12) years; 64% were women; 82.7% were White; 43.2% had been diagnosed with MDD ≥ 4 times; and 72.8% of participants had experienced 1 or more prior depressive episodes.

Results: HAM-D17 scores mean (SD) changes in MADRS total scores between weeks 0–14 were 0.1 (–1.8, 2.0) and –1.1 (–3.1, 0.9) for those taking LDX and placebo, respectively (P = .3199). No participants on LDX experienced serious TEAEs. The safety profile of LDX was consistent with prior LDX ADHD studies and long-acting stimulant use.

Conclusions: LDX augmentation therapy in adults with MDD and residual symptoms did not meet the primary endpoint of HAM-D17 score reduction. The safety profile of LDX was consistent with prior reports.

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