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INVESTIGATOR-RATED SYMPTOMATOLOGICAL OUTCOMES IN A PHASE 4 STUDY OF LISDEXAMFETAMINE DIMESYLATE IN ADULTS WITH ATTENTION-DEFICIT/HYPERACTIVITY DISORDER AND IMPAIRED EXECUTIVE FUNCTION.

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Introduction

Symptoms of attention-deficit/hyperactivity disorder (ADHD) appear in childhood, but are recognised as often persistent into adulthood. Impairments in day-to-day functioning associated with ADHD in adults include deficiency in executive function.

Objectives

Evaluate the effect of lisdexamfetamine dimesylate (LDX) on ADHD symptoms in adults with ADHD and executive function deficit.

Methods

This phase 4, randomized, double-blind study enrolled adults (aged 18–55) with baseline ADHD Rating Scale IV with Adult Prompts (ADHD-RS-IV-Adult) total score ≥28 and baseline Global Executive Composite T-score ≥65 on the Behaviour Rating Inventory of Executive Function–Adult Version. Patients were randomized 1:1 to receive optimized doses of LDX (30, 50 or 70 mg/day) or placebo for up to 10 weeks. The change from baseline in the investigator-rated ADHD-RS-IV-Adult total score was a secondary efficacy outcome.

Results

The full analysis set comprised 154 patients (LDX, n=79; placebo, n=75). At baseline, mean ADHD-RS-IV-Adult total score was 39.9 in both groups (standard deviation [SD]: LDX, 6.83; placebo, 7.37) and mean changes from baseline to week 10 or early termination were –21.4 (SD, 11.27) and –10.3 (12.70) in the LDX and placebo groups, respectively. Statistical analysis showed a significant difference (LDX minus placebo) in least-squares mean changes of –11.1 (95% confidence interval: –14.9, –7.3), with an effect size of 0.94 in favour of LDX (p<0.0001). Safety outcomes were consistent with previous studies and the known effects of stimulant treatment.

Conclusion

Short-term treatment with LDX markedly reduced ADHD symptoms in adults with ADHD and impaired executive function.

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