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EFFICACY OF LISDEXAMFETAMINE DIMESYLATE AND ATOMOXETINE IN CHILD AND ADOLESCENT SUBGROUPS FROM A HEAD-TO-HEAD, DOUBLE-BLIND, RANDOMIZED TRIAL IN PATIENTS WITH ATTENTION-DEFICIT/HYPERACTIVITY DISORDER

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#### Introduction

Symptoms of attention-deficit/hyperactivity disorder (ADHD) appear in childhood and may persist into adolescence and beyond.

## Objective

Evaluate the efficacy of lisdexamfetamine dimesylate (LDX) and atomoxetine in subgroups of children and adolescents with ADHD.

### Methods

In this 9-week, double-blind study, patients aged 6–17 with ADHD and an inadequate response to previous methylphenidate therapy were randomized (1:1) to optimized doses of LDX or atomoxetine. Efficacy measures included ADHD Rating Scale IV (ADHD-RS-IV) total score and dichotomized Clinical Global Impressions-Improvement (CGI-I) score (improved, 1–2; not improved, 3–7).

#### Results

The full analysis set (n=262) comprised 194 children aged 6–12 (LDX, n=93; atomoxetine, n=101) and 68 adolescents aged 13–17 (LDX, n=34; atomoxetine, n=34). Mean optimized doses were: LDX, 52.5 (SD, 16.10) mg/day; atomoxetine, 40.2 (20.05) mg/day. Baseline mean ADHD-RS-IV total score was similar across treatment and age groups. Table shows efficacy results; safety profiles were consistent with previous studies.

LDX Atomoxetine Mean change in ADHD-RS-IV total score by visit 9 (95% confidence interval) Overall -26.3 (-28.4, -24.2) -19.4 (-21.6, -17.2) -27.5 (-29.8, -25.1) -19.4 (-22.0, -16.7) Children Adolescents-22.9 (-27.3, -18.5) -19.5 (-23.7, -15.3) Patients (%) with improved CGI-I score by visit 9 (95% confidence interval) Overall 81.7 (75.0, 88.5) 63.6 (55.4, 71.8) 83.9 (76.4, 91.3) Children 61.2 (51.6, 70.9) Adolescents75.8 (61.1, 90.4) 70.6 (55.3, 85.9)

#### Conclusion

Within each treatment group, improvements in symptomatological scales and global improvement ratings were observed in children and adolescents.

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