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EFFICACY OUTCOMES IN AGE AND SEX SUBGROUPS FROM TWO CLINICAL TRIALS OF LISDEXAMFETAMINE DIMESYLATE IN THE TREATMENT OF ADULTS WITH ATTENTION-DEFICIT/HYPERACTIVITY DISORDER

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Introduction

Symptoms of attention-deficit/hyperactivity disorder (ADHD) persist into adulthood in many patients.

Aims/objectives

Analyse *post hoc* the impact of sex and age on the efficacy of lisdexamfetamine dimesylate (LDX) in the treatment of adult ADHD.

Methods

In NRP104.303, a 4-week, double-blind, forced-dose study, adults with ADHD were randomized (2:2:2:1) to receive LDX 30, 50 or 70 mg/day, or placebo. NRP104.304 was a 12-month, open-label, dose-optimized, extension to NRP104.303. In both studies, the primary efficacy outcome was the change from baseline in ADHD Rating Scale (ADHD-RS) total score.

Results

In NRP104.303 (N=420), least-squares mean changes from baseline to endpoint in ADHD-RS total score (standard error) were significantly greater for LDX (range across doses, –16.2 [1.06] to –18.6 [1.03]) than placebo (–8.2 [1.43]). *Post hoc* analyses revealed similar improvements with LDX in sex (male, LDX –16.7 [1.50] to –18.6 [1.53], placebo, –8.9 [2.12]; female, LDX –15.5 [1.56] to –19.3 [1.46], placebo –8.0 [2.02]) and age (18–39 years, LDX –15.3 [1.34] to –18.9 [1.31], placebo –5.6 [1.87]; 40–55 years, LDX –16.1 [1.81] to –17.1 [1.87], placebo –12.8 [2.52]) subgroups. In study NRP104.304 (N=349), improvements from baseline to endpoint in mean (standard deviation) ADHD-RS total score were similar between the overall population (–24.8 [11.7]) and sex and age subgroups (male –24.5 [11.5]; female –25.2 [12.0]; 18–39 years –25.3 [11.4]; 40–55 years –24.1 [12.2]).

Conclusions

In short- and long-term adult studies, LDX was associated with improvements in ADHD symptoms in sex and age-related subgroups.

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