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POST HOC ANALYSES ON THE EFFICACY OF LISDEXAMFETAMINE DIMESYLATE FOLLOWING PREVIOUS TREATMENT WITH ATTENTION DEFICIT/HYPERACTIVITY DISORDER MEDICATION

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Background: The prodrug lisdexamfetamine dimesylate (LDX) is licensed in several European countries for treating attention-deficit/hyperactivity disorder (ADHD) in children and adolescents with an inadequate response to methylphenidate (MPH) treatment.

Objectives/Aims: To evaluate *post hoc* the impact of ADHD medication history on the efficacy of LDX.

Methods: In this 7-week, dose-optimized, double-blind, study, patients (6–17 years) were randomized 1:1:1 to LDX, placebo or osmotic-release oral system methylphenidate (OROS-MPH). Efficacy assessments included ADHD Rating Scale IV (ADHD-RS-IV) and Clinical Global Impressions-Improvement (CGI-I) scores.

Results: The full analysis set (FAS) comprised 317 patients. Baseline characteristics were similar across treatment groups and previous treatment subgroups. At endpoint, the mean change from baseline in ADHD-RS-IV total score and proportions of responders based on a CGI-I of 1 or 2 for LDX, OROS-MPH and placebo are presented below.

Previous treatment sub-group	LDX	Placebo	OROS-MPH
Mean change (SD) in ADHD-RS-IV total score			
FAS (N=317)	–24.7 (10.15)	–6.3 (10.02)	–18.9 (12.92)
Treatment-naïve (n=147)	–24.0 (10.00)	–8.5 (10.34)	–21.4 (13.09)
Any previous ADHD medication (n=170)	–25.3 (10.34)	–4.2 (9.30)	–16.9 (12.53)
Previous MPH treatment (n=146)	–25.4 (10.67)	–4.7 (9.70)	–17.7 (11.96)
Proportion of responders (95% CI): CGI-I 1 or 2			
FAS (N=317)	78.0% (69.9, 86.1)	14.4% (7.7, 21.2)	60.6% (51.2, 70.0)
Treatment-naïve (n=147)	80.4% (69.0, 91.9)	19.6% (8.7, 30.5)	63.8% (50.1, 77.6)
Any previous ADHD medication (n=170)	75.9% (64.5, 87.3)	9.4% (1.6, 17.3)	57.9% (45.1, 70.7)

Conclusions: LDX and OROS-MPH were associated with clinically relevant improvements in ADHD symptoms irrespective of ADHD medication history.

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