Article: 957
Topic: 41 - Child and Adolescent Psychiatry

POST HOC COMPARISON OF THE EFFICACY OF LISDEXAMFETAMINE DIMESYLATE AND OSMOTIC-RELEASE ORAL SYSTEM METHLYPHENIDATE IN CHILDREN AND ADOLESCENTS WITH ADHD

D. Coghill[1], *T. Banaschewski*[2], *M. Lecendreux*[3], *C. Soutullo*[4], *M. Johnson*[5], *A. Zuddas*[6], *C. Anderson*[7], *R. Civil*[7], *N. Higgins*[7], *R. Bloomfield*[8], *L. Squires*[7]

[1]Division of Neuroscience, Ninewells Hospital, Dundee, UK, [2]Child and Adolescent Psychiatry and Psychotherapy, Central Institute of Mental Health, Medical Faculty Mannheim, University of Heidelberg, Mannheim, Germany, [3]Pediatric Sleep Center, CHU Robert Debré, Paris, France, [4]Child and Adolescent Psychiatry Unit, Department of Psychiatry and Medical Psychology, University Clinic of Navarra, Pamplona, Spain, [5]Child Neuropsychiatry Unit, Queen Silvia Children's Hospital, Gothenburg, Sweden, [6]Department of Biomedical Sciences, Section of Neuroscience and Clinical Pharmacology, University of Cagliari, Cagliari, Italy, [7]Shire Development LLC, Wayne, PA, USA, [8]Shire Pharmaceutical Development Ltd, Basingstoke, UK

Introduction: In a European, phase 3 study (SPD489-325), lisdexamfetamine dimesylate (LDX) and osmotic-release oral system methylphenidate (OROS-MPH) were more effective than placebo in improving core symptoms in children and adolescents with attention-deficit/hyperactivity disorder (ADHD).
Objectives and aims: To compare post hoc the efficacy of LDX and OROS-MPH in study SPD489-325.
Methods: This 7-week, randomized, double-blind, parallel-group, dose-optimized, placebo-controlled trial enrolled patients aged 6-17 years with ADHD of at least moderate severity. Patients were randomized (1:1:1) to receive a once-daily dose of LDX (30, 50, 70 mg/day), OROS-MPH (18, 36, 54 mg/day) or placebo. Efficacy was assessed using the ADHD Rating Scale version IV (ADHD-RS-IV) and the Clinical Global Impression-Improvement (CGI-I) scale. Endpoint was defined as the last on-therapy treatment visit with a valid assessment.
Results: The full analysis set comprised 317 patients (LDX, n=104; placebo, n=106; OROS-MPH, n=107). The difference between LDX and OROS-MPH in least squares mean change (95% confidence interval [CI]) in ADHD-RS-IV total score from baseline to endpoint was statistically significant in favour of LDX (-5.6 [-8.4, -2.7]; $p < 0.001$; effect size, 0.541). The difference (LDX minus OROS-MPH) in the percentage of patients (95% CI) with an improved CGI-I score at endpoint was also statistically significant in favour of LDX (17.4 [5.0, 29.8]; $p < 0.05$).
Conclusions: This post hoc analysis indicated that LDX is significantly more effective than OROS-MPH in improving core symptoms and global functioning in children and adolescents with ADHD.
Supported by: Funding from Shire Development LLC.