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<sup>1</sup>, T. Banaschewski<sup>2</sup>, M. Lecendreux<sup>3</sup>, C. Soutullo<sup>4</sup>, M. Johnson<sup>5</sup>, A. Zuddas<sup>6</sup>, C. Anderson<sup>7</sup>, R. Civil<sup>7</sup>, N. Higgins<sup>7</sup>, R. Bloomfield<sup>8</sup>, L. Squires<sup>7</sup>

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