Article: EPA-0994

Topic: S537 - Effectiveness of stimulant treatment in attention-deficit/hyperactivity disorder: functional, health-related quality of life and

health utility outcome measures

Assessing ADHD stimulant treatment efficacy using the Weiss Functional Impairment Rating Scale: strengths and weaknesses

C. Soutullo<sup>1</sup>, T. Banaschewski<sup>2</sup>, M. Lecendreux<sup>3</sup>, M. Johnson<sup>4</sup>, A. Zuddas<sup>5</sup>, P. Hodgkins<sup>6</sup>, B. Adeyi<sup>7</sup>, L.A. Squires<sup>8</sup>, D.R. Coghill<sup>9</sup>

<sup>1</sup>Department of Psychiatry and Medical Psychology, University of Navarra Clinic, Pamplona, Spain; <sup>2</sup>Child and Adolescent Psychiatry and

Psychotherapy, University of Heidelberg, Mannheim, Germany; <sup>3</sup>Paediatric Sleep Centre and National Reference Centre for Orphan Diseases:

Narcolepsy Idiopathic Hypersomnia and Kleine-Levin Syndrome, Robert-Debré University Hospital, Paris, France; 4Child Neuropsychiatry Unit,

Queen Silvia Children's Hospital, Gothenburg, Sweden; 5Department of Biomedical Sciences, University of Cagliari, Cagliari, Italy; 6Global

Health Economics and Outcomes Research, Shire Development LLC, Wayne, USA; <sup>7</sup>Global Biostatistics, Shire Development LLC, Wayne, USA

; 8Global Clinical Development and Innovation, Shire Development LLC, Wayne, USA; 9Division of Neuroscience, University of Dundee, Dundee,

United Kingdom

# Introduction

The Weiss Functional Impairment Rating Scale—Parent Report (WFIRS-P) is an ADHD-specific instrument comprising 50 items, grouped into six domains. Parents score each item on a Likert scale (0–3 or not applicable).

## Objective

To evaluate functional impairment using the WFIRS-P in two phase 3 studies (SPD489-325 and SPD489-326) of lisdexamfetamine dimesylate (LDX) in children and adolescents with ADHD.

#### Methods

Patients' parents or guardians completed WFIRS-P assessments at baseline, and weeks 4 and 7 of SPD489-325, a 7-week, randomized, placebo controlled trial incorporating a reference treatment (osmotic-release oral system methylphenidate; OROS-MPH). Statistical comparison of LDX versus OROS-MPH was not pre-specified. In SPD489-326, WFIRS-P assessments were performed in the ≥26-week open-label period and the subsequent 6-week randomized-withdrawal period.

## Results

In SPD489-325, statistically significant placebo-adjusted effects of LDX were observed in WFIRS-P total score (effect size, 0.924; *p*<0.001) and in Family, Learning and School, Social Activities and Risky Activities; OROS-MPH effects were significant in total score (effect size 0.772; *p*<0.001) and in all domains. In SPD489-326, scores were improved or stable in the open-label period. In the randomized-withdrawal period, total score and all domain scores were stable in the LDX group, but worsened in the placebo group. LDX was significantly more effective than placebo in Family, Learning and School, Risky Activities and in total score (effect size, 0.908; *p*<0.001).

# Conclusions

Short-term treatment with LDX or OROS-MPH led to improved functional impairment scores. These benefits were maintained during long-term LDX treatment, and scores declined following treatment withdrawal.

Supported by funding from Shire.