variables during the internal process of therapy (e.g., involvement of patient, therapist and their relationship). What is the role of mediators of change, specifically relative to a dysfunction (e.g., affect modula- tion) or a stage of therapy, or of contextual factors of psychotherapy (e.g., family alliance)? Finally, are some factors predictive of an evolution rather than another? The method is that of comparison of patients initially similar by diagnosis, age and initial severity of the disorder.

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Lisdexamfetamine Dimesylate for ADHD

Tu-S-327
The first European study of lisdexamfetamine dimesylate in children and adolescents with ADHD: Overview
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In this 7-week study, participants (6–17 years, n = 336) with attention-deficit/hyperactivity disorder (ADHD) were randomized to lisdexamfetamine dimesylate (LDX), placebo or osmotic-release oral-system methylphenidate (OROS-MPH; reference arm). The primary efficacy measure was the investigator-rated ADHD-rating scale-IV (ADHD-RS-IV). Safety assessments included treatment-emergent adverse events (TEAEs) and vital signs. Baseline mean (±SD) ADHD-RS-IV total scores were 40.7 ± 7.3 (LDX), 41.0 ± 7.1 (placebo) and 40.5 ± 6.7 (OROS-MPH). At endpoint, the difference between LDX and placebo in least squares (LS) mean change from baseline (95% confidence intervals) in ADHD-RS-IV total score was –18.6 (–21.5, –15.7; P < 0.001; effect size, 1.263). The most common TEAEs for LDX were decreased appetite, headache and insomnia. LDX was effective and generally well tolerated in children and adolescents with ADHD.

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Tu-S-328
Duration of response of lisdexamfetamine dimesylate in children and adolescents with ADHD
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In this 7-week study, participants (6–17 years, n = 336) with attention-deficit/hyperactivity disorder (ADHD) were randomized to lisdexamfetamine dimesylate (LDX), placebo or osmotic-release oral-system methylphenidate (OROS-MPH; reference arm). Functional impairment was assessed at baseline, day 28 and day 49 using Conners’ Parent Rating Scale–Revised (CPRS–R). At endpoint, differences (active–placebo) in least squares mean change from baseline (95% confidence intervals) in CPRS–R scores were significant (P < 0.001) for LDX (10:00 hrs, –21.5 [–25.8, –17.1], effect size [ES] 1.424; 14:00 hrs, –22.1 [–26.7, –17.6], ES 1.411; 18:00 hrs, –21.2 [–25.8, –16.5], ES 1.300) and OROS-MPH (10:00 hrs, –15.6 [–20.0, –11.2], ES 1.036; 14:00 hrs, –15.3 [–19.7, –10.9], ES 0.976; 18:00 hrs, –15.0 [–19.7, –10.3], ES 0.922). In children and adolescents receiving a single morning dose (07:00 hrs) of LDX, improvements in ADHD-related symptoms and behaviours were maintained until 18:00 hrs.

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Tu-S-329
Effect of lisdexamfetamine dimesylate on functional impairment in children and adolescents with ADHD
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In this 7-week study, participants (6–17 years, n = 336) with attention-deficit/hyperactivity disorder (ADHD) were randomized to lisdexamfetamine dimesylate (LDX), placebo or osmotic-release oral-system methylphenidate (OROS-MPH; reference arm). Functional impairment was assessed at baseline, day 28 and day 49 using the Weiss Functional Impairment Rating Scale-Parent (WFIRS-P). Mean (±SD) WFIRS-P total scores at baseline were 1.01 ± 0.45 (LDX), 1.10 ± 0.46 (placebo) and 1.07 ± 0.44 (OROS-MPH). At endpoint, the difference between LDX and placebo in least squares (LS) mean change from baseline (95% confidence intervals) in WFIRS-P total score was –0.3 (–0.4, –0.2; P < 0.001; effect size, 0.924). The difference between OROS-MPH and placebo in LS mean change from baseline was –0.2 (–0.3, –0.1; P < 0.001; effect size, 0.772). LDX was significantly more effective than placebo in improving functional impairments in children and adolescents with ADHD. Supported by funding from Shire Development LLC.

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