ABSTRACT

Objectives:
To determine the efficacy and safety of amphetamine extended-release oral suspension (AMPH EROS) in the treatment of attention-deficit/hyperactivity disorder (ADHD) in a dose-optimized, randomized, double-blind, parallel-group study.

Methods:
Boys and girls aged 6 to 12 years diagnosed with ADHD were enrolled. During a 5-week, open-label, dose-optimization phase, patients began treatment with 2.5 or 5 mg/day of AMPH EROS; doses were titrated until an optimal dose (maximum 20 mg/day) was reached. During the double-blind phase, patients were randomized to receive treatment with either their optimized dose (10–20 mg/day) of AMPH EROS or placebo for 1 week. Efficacy was assessed in a laboratory classroom setting on the final day of double-blind treatment using the Swanson, Kotkin, Agler, M-Flynn, and Pelham (SKAMP) Rating Scale and Permanent Product Measure of Performance (PERMP) test. Safety was assessed measuring adverse events (AEs) and vital signs.

Results:
The study was completed by 99 patients. The primary efficacy endpoint (change from predose SKAMP-Combined score at 4 hours postdose) and secondary endpoints (change from predose SKAMP-Combined scores at 1, 2, 6, 8, 10, 12, and 13 hours postdose) were statistically significantly improved with AMPH EROS treatment versus placebo at all time points. Onset of treatment effect was present by 1 hour postdosing, the first time point measured, and duration of efficacy lasted 13 hours postdosing. PERMP data mirrored the SKAMP-Combined score data. AEs (>5%) reported during dose optimization were decreased appetite, insomnia, affect lability, upper abdominal pain, mood swings, and headache.

Conclusion:
AMPH EROS was effective in reducing symptoms of ADHD and had a rapid onset and extended duration of effect. Reported AEs were consistent with those of other extended-release amphetamine products.