Efficacy, Safety, and Tolerability of an Extended-Release Orally Disintegrating Methylphenidate Tablet in Children 6–12 Years of Age with Attention-Deficit/Hyperactivity Disorder in the Laboratory Classroom Setting

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ABSTRACT

Objective: Methylphenidate extended-release orally disintegrating tablets (MPH XR-ODTs) represent a new technology for MPH delivery. ODTs disintegrate in the mouth without water and provide a pharmacokinetic profile that is consistent with once-daily dosing. This study sought to determine the efficacy, safety, and tolerability of this novel MPH XR-ODT formulation in school-age children with attention-deficit/hyperactivity disorder (ADHD) in a laboratory classroom setting.

Methods: Children aged 6–12 years with ADHD (n = 87) were enrolled in this randomized, multicenter, double-blind, placebo-controlled, parallel, laboratory classroom study. The MPH XR-ODT dose was titrated to an optimized dose during a 4-week open-label period and maintained on that dose for 1 week. Participants (n = 85) were then randomized to receive their optimized dose of MPH XR-ODT or placebo once daily for 1 week (double blind), culminating in a laboratory classroom testing day. Efficacy was evaluated using the Swanson, Kotkin, Agler, and Pelham (SKAMP) Attention, Deportment, and Combined scores along with Permanent Product Measure of Performance (PERMP; Attempted and Correct) assessments. Onset and duration of drug action were also evaluated as key secondary endpoints. Safety assessments included adverse events (AEs), physical examinations, electrocardiograms (ECGs), and the Columbia Suicide Severity Rating Scale (C-SSRS).

Results: The average SKAMP-Combined score on the classroom study day was significantly better for the MPH XR-ODT group (n = 43) than for the placebo group (n = 39; p < 0.0001). The effect was evident at 1 hour and lasted through 12 hours postdose. The average SKAMP-Attention, SKAMP-Deportment, PERMP-A, and PERMP-C scores were indicative of significantly greater ADHD symptom control for the MPH XR-ODT group. The most common AEs reported were decreased appetite, upper abdominal pain, headache, insomnia, upper respiratory tract infection, affect lability, irritability, cough, and vomiting.

Conclusions: MPH XR-ODT was effective and well tolerated for the treatment of children with ADHD in a laboratory classroom setting.

Clinical Trial Registry: NCT01835548 (ClinicalTrials.gov).