A Long-Term, Open-Label, Safety Study of Triple-Bead Mixed Amphetamine Salts (SHP465) in Adults with ADHD

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Abstract

Objective:
The aim of this study was to evaluate the long-term safety of triple-bead mixed amphetamine salts (MAS) in adults with ADHD.

Method:
Adults meeting Diagnostic and Statistical Manual of Mental Disorders (4th ed., text rev.; DSM-IV-TR) ADHD criteria and satisfying study criteria from one of two antecedent studies were enrolled in this 52-week (dose titration, 4 weeks; dose maintenance, 11 months) open-label extension. The protocol included 12.5- to 75-mg triple-bead MAS but was amended to a maximum of 50-mg triple-bead MAS. Safety evaluations included treatment-emergent adverse events (TEAEs) and vital signs. Clinical outcome measures included ADHD Rating Scale–IV (ADHD-RS-IV) total score changes.

Results:
Of 505 enrolled participants, 266 completed the study; the M ± SD daily dose during the study was 48.0 ± 15.96 mg. The most frequent TEAEs were insomnia (initial insomnia, insomnia, early morning awakening, middle insomnia; 38.2%), headache (25.7%), and dry mouth (20.2%). Study discontinuations were more frequent with higher doses of triple-bead MAS (37.5-75 mg) than with lower doses (12.5 and 25 mg). Blood pressure and pulse increases were observed at end-of-study. Mean ADHD-RS-IV total score decreases from the antecedent study and open-label baselines at end-of-study were −23.3 ± 11.44 and −7.9 ± 13.19, respectively.

Conclusion:
Triple-bead MAS exhibited a long-term safety profile comparable with previous reports and demonstrated evidence of continued symptom control for up to 12 months.