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EFFECTS OF PLACEBO-CONTROLLED WITHDRAWAL AFTER LONG-TERM OPEN LABEL TREATMENT WITH OROS MPH IN ADULTS WITH ADHD

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Objective: To explore maintenance of effect with OROS MPH in adults with ADHD.

Methods: Multicenter study randomizing adult subjects with ADHD who completed open-label (OL) treatment with OROS MPH (18-90mg/day) for at least 52-week and consented to a 4-week, randomized, double-blind (DB), placebo-controlled (PLC) withdrawal period. Efficacy measures included total CAARS score, CAARS-S:S, GAE, CGI-S and CGI-C. Endpoint analyses were performed using LOCF.

Results: 99/155 patients completed the OL OROS MPH treatment phase, only 45/99 patients consented to double-blind randomization. At DB baseline, mean ± SD TCS was 12.1±5.34 (n=23) in the continued OROS MPH group and 16.5±7.49 (n=22) in the placebo group. CAARS changed from DB baseline to DB endpoint by 4.0±7.61 and 6.5±7.82, respectively (p = 0.2586 between groups). CGI-C scores indicated more worsening of symptoms in the placebo group compared to the continued PR OROS MPH (p = 0.0422). Median (range) GAE scores at endpoint were 2.0 (0-3) and 0.5 (0-3), respectively (p=0.0254). Other efficacy endpoints were numerically in favor of OROS MPH. The randomized withdrawal phase may have been underpowered to show statistical significance between treatment groups for the primary outcome. The incidence of treatment-emergent AEs during the DB phase was comparable between groups.

Conclusions: The results indicate that treatment discontinuation after long-term exposure of adults with ADHD to OROS MPH is associated with worsening of clinical symptoms. Statistical significance for several outcomes was not reached, possibly due to study limitations.

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