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EFFECTS OF OROS-MPH ON ADULT PATIENTS WITH ADHD - RESULTS OF THE GERMAN SUBPOPULATION OF THE EUROPEAN LAMDA TRIAL (42603ATT3002/-3004)

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Although well-studied in children, MPH is not approved for the treatment of ADHD in adults in Germany. We report the findings from the German subgroup of the European LAMDA trial.

Patients (18-65 years) with ADHD (DSM-IV) were treated in this 5-week double-blind, randomized, placebo-controlled, fixed dose trial with 18, 36, 72-mg/day OROS-MPH or placebo. Eligible patients continued into the subsequent 7-week open-label extension-phase starting with 18 mg/day OROS-MPH.

108 patients entered the double-blind phase, which was completed by 89.9%. The open-label phase was completed by 92.6%. Concerning CAARS:O-SV total scores (LOCF), mean changes from baseline to double-blind endpoint in were -9.6 ± 10.6 (18-mg), -13.3 ± 10.3 (36-mg) and -12.7 ± 10.7 (72-mg) vs. -8.2 ± 8.4 (placebo group). Mean changes from start of open-label phase to endpoint were -17.5 in patients who received OROS-MPH and -16.5 , who received placebo in double-blind phase. Mean Q-LES-Q-SF scores (health-related QoL) improved from baseline in all treatment groups in the double-blind phase, and continued to improve in the open-label phase. AE occurred in 77.4% (18-mg), 85.7% (36-mg), 77.4% (72-mg) and 65.5% (placebo group). Most common AE were decreased appetite, headache, nasopharyngitis and weight decreased. No statistically significant changes in mean blood pressure were observed in the double-blind or open-label phases. Mean pulse increased by 7.0 bpm (72-mg group) at week 5 ($p=0.025$) and by 7.9 bpm in all patients at week 12 ($p < 0.001$).

This analysis of the German subpopulation is in line with results of the full study, showing that OROS-MPH is effective and well tolerated in adults with ADHD.