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# GUANFACINE XR (GXR) FOR CHILDREN AND ADOLESCENTS WITH ATTENTION-DEFICIT/HYPERACTIVITY DISORDER (ADHD): PHASE 3, BLIND, MULTICENTER, PLACEBO- AND ACTIVE-REFERENCE STUDY

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**Introduction:** GXR, a selective α2A-adrenergic agonist, is a non-stimulant treatment for ADHD (approved in the USA for children and adolescents a

**Objectives:** To assess the efficacy (symptoms and function) and safety of dose-optimized GXR compared with placebo in children and adolescents

**Aims:** To evaluate the efficacy (symptom and function) and safety of GXR for the treatment of ADHD. An atomoxetine (ATX) arm was included to pr placebo (NCT01244490).

**Methods:** Patients (6–17 years) were randomly assigned at baseline to dose-optimized GXR (6–12 years, 1–4 mg/day; 13–17 years, 1–7 mg/day), A for 4 or 7 weeks. The primary efficacy measure is change from baseline in ADHD-Rating Scale-version IV (ADHD-RS-IV). Key secondary measures Impressions-Improvement (CGI-I) and the Weiss Functional Impairment Rating Scale-Parent (WFIRS-P). Safety assessments included treatment-en (TEAEs), electrocardiograms, and vital signs.

**Results:** Of 338 patients randomized, 272 (80.5%) completed the study. Placebo-adjusted differences in least squares (LS) mean in ADHD-RS-IV t versus placebo for CGI-I, placebo-adjusted differences in LS mean change from baseline in WFIRS-P score (family and learning and school domains most common TEAEs for GXR were somnolence, headache, and fatigue; 8 (7%) TEAEs were severe.

**Conclusions:** GXR was effective and well tolerated in children and adolescents with ADHD.

| | GXR | ATX |
|---|---|---|
| Placebo-adjusted difference in LS mean change from baseline in ADHD-RS-IV total score (95% CI, p-value; effect size) | −8.9 (−11.9, -5.8, p<0.001; 0.76) | −3.8 (−6.8, −0.7, p<0.05; 0.32) |
| Difference in improvement from placebo for CGI-I (95% CI, p-value) | 23.7% (11.1, 36.4; p<0.001) | 12.1% (−0.9, 25.1; p<0.05) |
| Placebo-adjusted difference in LS mean change from baseline in WFIRS-P; learning and school domain score (95%CI, p-value; effect size) | −0.22 (−0.36, −0.08, p<0.01; 0.42) | −0.16 (−0.31, −0.02, p<0.05; 0.32) |
| Placebo-adjusted difference in LS mean change from baseline in WFIRS-P; family domain score (95%CI, p-value; effect size) | −0.21 (−0.36, −0.06, p<0.01; 0.38) | −0.09 (−0.24, 0.06, p=0.242; 0.16) |

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