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SAFETY, TOLERABILITY AND EFFICACY OF FLEXIBLE DOSES OF PALIPERIDONE ER IN NON-ACUTE PATIENTS WITH SCHIZOPHRENIA

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Objective: To explore tolerability, safety and efficacy of flexible doses of oral paliperidone ER in adult non-acute patients with schizophrenia requiring a change in their medication due to lack of efficacy with their previous oral antipsychotic.

Methods: Interim analysis of a prospective 6-month, open-label, international study. Patients completing the first 3 months of this study were analyzed. Endpoints were the change in the Positive and Negative Syndrome Scale (PANSS) from baseline to endpoint, Clinical Global Impression-Severity Scale (CGI-S), weight change and adverse events (AEs).

Results: 81 patients were included (57% male, mean age 41.3±13.6 years, 85% paranoid schizophrenia). 89% of the 81 patients completed the first 3 months of the study. Reasons for early discontinuation were lack of efficacy (3.7%), subject choice (2.5%), loss to follow-up (2.5%) and AE (1.2%). The mean mode dose of paliperidone ER was 6 mg/day. Mean total PANSS decreased from 82.8±16.0 at baseline to 69.2±19.1 at endpoint (mean change -13.6±15.6; 95% confidence interval [CI]-17.0;-10.1, p< 0.0001). The percentage of patients rated mildly ill or less in CGI-S increased from 19.8% to 49.4%. AEs reported in ≥3% were insomnia (4.9%), somnolence (4.9%), extrapyramidal disorder (3.7%), restlessness (3.7%) and psychotic disorder (3.7%). Mean weight change from baseline to endpoint was 0.34 kg (95%CI -0.35;1.03, p=0.71).

Conclusion: These interim open-label data support results from recent randomized controlled studies that flexibly dosed paliperidone ER is safe, well tolerated and effective in patients with schizophrenia requiring a change in medication due to lack of efficacy with their previous oral antipsychotic treatment.

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