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A FLEXIBLE-DOSE STUDY OF PALIPERIDONE ER IN NON-ACUTE PATIENTS WITH SCHIZOPHRENIA PREVIOUSLY UNSUCCESSFULLY TREATED WITH OTHER ORAL ANTIPSYCHOTICS

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Objective: To explore tolerability, safety and treatment response of flexible doses of paliperidone ER in adult non-acute patients with schizophrenia previously unsuccessfully treated with oral antipsychotics.

Methods: International prospective 6-month open-label study. Endpoints were the Positive and Negative Syndrome Scale (PANSS), Clinical Global Impression-Severity Scale (CGI-S), patient satisfaction, adverse events (AEs), extrapyramidal symptoms (Extrapyramidal Symptom Rating Scale; ESRS) and weight change.

Results: 1812 patients were included (59.9% male, mean age 40.1±12.6 years, 75.8% paranoid schizophrenia); most were enrolled because of lack of efficacy (n=1026) or lack of tolerability (n=490) with prior antipsychotic treatment. The median mode dose of paliperidone ER was 6 mg/day. 70.7% of patients completed the 6-month study. Most frequent reasons for early discontinuation were patient choice (8.8%), lack of efficacy or adverse event (5.1% each) independent of the reason for switching. Mean total PANSS decreased significantly from 79.4±20.4 at baseline to 66.1±21.5 at endpoint (mean change -13.3±19.7; 95% confidence interval -14.2;-12.3, $p < 0.0001$). The percentage of patients rated mildly ill or less in CGI-S increased from 27.0% to 52.2% at endpoint, and the rate of patients with mild functional impairment increased from 15.8% to 34.9%. AEs reported in greater-than-or-equal-to 5% of patients were insomnia (9.2%) and anxiety (7.2%). Extrapyramidal symptoms in ESRS decreased significantly from 3.5±5.8 to 2.1±4.6 ($p < 0.0001$). Mean weight gain from baseline to endpoint was 0.3±4.8kg.

Conclusion: These data support results from recent randomized controlled studies that paliperidone ER is safe, well tolerated and effective in patients previously unsuccessfully treated with other oral antipsychotics.

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