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# SAFETY, TOLERABILITY AND TREATMENT RESPONSE WITH FLEXIBLE DOSES OF PALIPERIDONE PALMITATE IN NON-ACUTE PATIENTS WITH SCHIZOPHRENIA

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**Objective:** To explore tolerability, safety and treatment response of flexible doses of paliperidone palmitate in adult non-acute patients with schizophrenia previously unsuccessfully treated with oral antipsychotics.
**Methods:** Interim analysis of a prospective 6-month, open-label study. Outcomes were change in the Positive and Negative Syndrome Scale (PANSS) score, Clinical Global Impression-Severity Scale (CGI-S) and patient functioning (Personal and Social Performance Scale; PSP) from baseline to endpoint, weight change and adverse events (AEs).
**Results**: Of the first 403 patients enrolled (63.3% male, mean age 39.4±12.0 years). 74.4% completed the study. Most frequent reasons for discontinuation were subject choice (10.7%), and AE (5.5%). The recommended initiation regimen was administered in 94.0% of subjects. Mean PANSS total score decreased from 71.9±15.2 at baseline to 60.8±18.4 at endpoint (mean change -11.1±15.4; 95% confidence interval [CI]-12.6;-9.6; p< 0.0001); 61.2% of the patients showed an improvement of ≥20% in PANSS total score. The percentage of patients rated mildly ill or less in CGI-S increased from 33.2% to 62.1%. Patient functioning improved from a mean PSP baseline score of 57.9±13.7 to 65.2±15.3 at endpoint (95%CI of change 6.0; 8.7; p< 0.0001). AEs reported in ≥5% were injection site pain (13.9%), insomnia (7.9%), anxiety (6.9%), psychotic disorder (5.7%) and somnolence (5.2%). Mean weight change from baseline to endpoint was 1.4±5.2kg (95%CI 0.8; 1.9).
**Conclusion:** These data support results from recent randomized controlled studies that flexibly dosed paliperidone palmitate is safe, well tolerated and associated with a clinically relevant treatment response in non-acute patients with schizophrenia previously unsuccessfully treated with oral antipsychotics.