

## Tolerability, Safety and Treatment Response of Flexibly-dosed Paliperidone Palmitate in Patients Hospitalized for an Exacerbation of Schizophrenia

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**OBJECTIVE:** To explore tolerability, safety and treatment response of flexibly-dosed paliperidone palmitate (PP) in adult patients hospitalized for an exacerbation of schizophrenia.

**METHODS:** International 6-week prospective open-label non-interventional study. Outcome parameters were changes in Brief Psychiatric Rating Scale (BPRS) total score, Clinical Global Impression-Severity Scale (CGI-S), Personal and Social Performance Scale (PSP), treatment satisfaction (Medication Satisfaction Questionnaire (MSQ)), Extrapyramidal Symptom Rating Scale (ESRS) scores and treatment-emergent adverse events (TEAEs) from baseline to last-observation-carried-forward endpoint.

**RESULTS:** 367 patients (65.9% male, mean age ( $\pm$ SD) 39.8 $\pm$ 12.1 years, 85.8% paranoid schizophrenia) were documented. 91.6% completed the 6-week observation period. Mean time from hospital admission to initiation of PP was 9.4 $\pm$ 7.7 days. Mean baseline BPRS total score of 50.2 $\pm$ 13.6 improved by -6.5 $\pm$ 8.6 at day 8 and by -19.3 $\pm$ 12.6 at endpoint; 95% confidence interval [CI]-20.7;-18.0; both  $p < 0.0001$ . At endpoint, 93.6% of patients were rated as improved in CGI-S. Functioning in PSP significantly improved from 49.4 $\pm$ 14.7 at baseline by 14.3 $\pm$ 12.4 at endpoint (95% CI 12.9;15.8,  $p < 0.0001$ ). Mean ESRS total score significantly decreased from 3.7 $\pm$ 5.9 at baseline to 2.0 $\pm$ 4.7 at endpoint ( $p < 0.0001$ ). 6.0% of patients were very or extremely satisfied with their previous antipsychotic medication at baseline, and 46.1% with PP at endpoint. TEAEs reported in  $\geq 2\%$  of patients were tremor (2.5%) and schizophrenia (2.2%).

**CONCLUSIONS:** These data support results from previous randomized controlled and pragmatic studies that flexibly dosed paliperidone palmitate is well tolerated and associated with an early and clinically meaningful treatment response and functional improvement in patients hospitalized for an exacerbation of schizophrenia.