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SAFETY, TOLERABILITY AND TREATMENT RESPONSE WITH FLEXIBLE DOSES OF PALIPERIDONE PALMITATE IN PATIENTS WITH AN ACUTE EXACERBATION OF SCHIZOPHRENIA

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Objective: To explore tolerability, safety and treatment response with flexible doses of paliperidone palmitate in adult patients with an acute episode of schizophrenia.
Methods: Interim analysis of a prospective 6-month, open-label, multicenter study in adult patients with schizophrenia. Outcomes were change in the Positive and Negative Syndrome Scale (PANSS) total score from baseline to endpoint, Clinical Global Impression-Severity Scale (CGI-S), patient functioning (Personal and Social Performance Scale; PSP), weight change and adverse events (AEs).
Results: Of the first 104 patients included (54.8% male, mean age 37.6±11.8 years, 81.7% paranoid schizophrenia, recommended paliperidone palmitate initiation regimen used in 89% of subjects), 65.4% completed the study. Most frequent reasons for discontinuation were AE (13.5%), subject choice (8.7%) and loss to follow-up (5.8%). Mean total PANSS score decreased from 99.5±15.5 at baseline to 71.0±26.9 at endpoint (mean change -28.6±26.2; 95% confidence interval [CI] -33.8; -23.4; p< 0.0001) with 60.6% of the patients showing improvement of ≥30%. Mean CGI-S score changed from 5.0±0.8 at baseline to 3.6±1.3 at endpoint (95%CI -1.7; -1.1; p< 0.0001). Patient functioning improved from a mean PSP baseline score of 42.7±13.9 to 59.0±18.7 at endpoint (95% CI of change 12.7; 19.9; p< 0.0001). AEs reported in ≥5% were psychotic disorder (15.4%), insomnia (14.4%), injection site pain (13.5%), headache (8.7%), salivary hypersecretion (6.7%) and anxiety (6.7%).
Conclusion: These data support results from recent randomized controlled studies that flexibly dosed paliperidone palmitate is safe, well tolerated and associated with clinically meaningful treatment response in patients suffering from an acute episode of schizophrenia.

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