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PALIPERIDONE PALMITATE IN ACUTE PATIENTS WITH SCHIZOPHRENIA: TREATMENT RESPONSE, SAFETY AND TOLERABILITY ? A PROSPECTIVE FLEXIBLE-DOSE STUDY IN PATIENTS PREVIOUSLY UNSUCCESSFULLY TREATED WITH ORAL ANTIPSYCHOTICS

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INTRODUCTION: This study explores tolerability, safety and treatment response of flexible doses of the atypical long-acting antipsychotic paliperidone palmitate (PP) in adult patients with an acute exacerbation of schizophrenia previously unsuccessfully treated with oral antipsychotics.

METHODS: International prospective open-label 6-month study. Outcome parameters were change in Positive and Negative Syndrome Scale (PANSS) total score, Clinical Global Impression-Severity Scale (CGI-S), treatment-emergent adverse events (TEAEs) and weight change.

RESULTS: 212 acute patients, 59.0% male, mean age 36.4 ±12.1 years, 85.4% paranoid schizophrenia were enrolled. 70.3% of patients completed the study. Most frequent reasons for early discontinuation were subject choice (9.4%), or an adverse event (9.0%). Recommended initiation regimen of PP (150 mg eq on day 1 and 100 mg eq on day 8) was administered in 92.9% of subjects. Mean baseline PANSS total score decreased from 98.5±20.1 as of day 8 of treatment to 67.4±24.0 at endpoint (mean change -31.0±28.97; 95% confidence interval [CI]-35.0;-27.1; p<0.0001). 66.7% of patients improved ≥30% in PANSS total score and percentage of patients rated markedly ill or worse in CGI-S decreased from 75.1% at baseline to 20.5% at endpoint. TEAEs reported in ≥5% were injection site pain (13.7%), insomnia (10.8%), psychotic disorder (10.4%), headache (6.1%) and anxiety (6.1%). Mean weight change at endpoint was 2.6±5.6 kg (95%CI 1.8; 3.4).

CONCLUSIONS: These data support results from previous randomized controlled studies that flexibly dosed paliperidone palmitate is well tolerated and associated with an early and clinically relevant treatment response in acute schizophrenia patients previously unsuccessfully treated with oral antipsychotics.

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