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PALIPERIDONE PALMITATE IN NON-ACUTE BUT SYMPTOMATIC PATIENTS WITH SCHIZOPHRENIA PREVIOUSLY UNSUCCESSFULLY TREATED WITH ORAL ARIPIPRAZOLE

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INTRODUCTION: To explore tolerability, safety and treatment response of flexibly dosed once-monthly paliperidone palmitate (PP) in adult non-acute patients with schizophrenia previously unsuccessfully treated with oral aripiprazole.

METHODS: International prospective open-label 6-month study. Outcomes were change in Positive and Negative Syndrome Scale (PANSS), patient functioning (Personal and Social Performance Scale; PSP), disease severity (CGI-S and CGI-C), Extrapyramidal Symptom Rating Scale (ESRS) and treatment-emergent adverse events (TEAEs).

RESULTS: 46 patients (73.9% male, mean age 34.4±9.4 years, 78.3% paranoid schizophrenia) were analyzed. The mean prior oral aripiprazole dose was 22.7±10.7 mg/day. 67.4% of patients completed the study. Mean PANSS total score decreased from 74.7±14.9 at baseline to 62.6±16.5 at LOCF endpoint (mean change -12.2±16.7; 95% confidence interval -17.1;-7.2; p<0.0001). 52.2% of patients showed a ≥20% improvement in PANSS total score, the percentage of patients rated mildly ill or less in CGI-S increased from 23.9% to 56.5% and 75.5% of patients were rated improved in CGI-C. Patient functioning in PSP improved from 58.9±13.4 to 62.9±15.2 (p=0.041). TEAEs reported in ≥5% were anxiety (n=6), injection site pain, bronchitis, insomnia and akathisia (n=4 each), and weight increase, depression and pain in extremities (n=3 each). Extrapyramidal symptoms measured by ESRS total scores improved significantly in completers from baseline to month 6 by -1.4±2.7 (p<0.007) and by -0.6±3.4 from baseline to LOCF endpoint (p=0.046).

CONCLUSIONS: Flexibly dosed paliperidone palmitate was well tolerated and associated with a clinically relevant symptomatic treatment response, improved functioning and less EPS in non-acute patients with schizophrenia previously unsuccessfully treated with oral aripiprazole.

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