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Efficacy and Safety of Paliperidone Palmitate 3-month Formulation in Schizophrenia: a Randomized, Double-blind, Placebo-controlled Study

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Aim:

This double-blind (DB), relapse prevention, phase-3 study was designed to evaluate the efficacy and safety of paliperidone palmitate long-acting 3-monthly formulation (PP3M) versus placebo in delaying time-to-relapse of schizophrenia symptoms.

Methods:

Adults (18-70 years old) with schizophrenia (DSM-IV-TR) were treated with PP (17-week, open-label [OL] transition phase: 50, 75, 100, or 150 mg eq, once-monthly, [PP1M]; 12-week OL maintenance phase: 3.5-fold PP1M stabilized dose, single injection), and then randomized (1:1) to PP3M fixed doses (175, 263, 350 or 525 mg eq.) or placebo.

Results:

305/506 patients enrolled were randomized (PP3M: n=160; placebo: n=145); majority were men (75%), white (59%), mean age 38.4 years. Interim analysis results favored PP3M vs. placebo ($p = 0.0002$, two-sided log-rank test; HR: 3.45, 95% CI: 1.73; 6.88); median time-to-relapse was 274 days in placebo and not estimable in PP3M group. Final results were consistent with interim analysis. Both PANSS total score and CGI-S score showed a significant effect over time in PP3M- vs. placebo-treated patients ($p < 0.001$). 330/506 (65.2%) patients in OL phase and 183/305 (60.0%) in DB phase (PP3M: 61.9% vs. placebo: 57.9%) had ≥ 1 treatment-emergent adverse event (TEAE). The TEAEs noted more frequently in PP3M-vs. placebo (DB phase) were nasopharyngitis (5.6% vs. 1.4%), weight gain (8.8% vs. 3.4%), headache (8.8% vs. 4.1%) and akathisia (4.4% vs. 0.7%).

Conclusion:

Compared with placebo, PP3M significantly delayed time to first relapse in patients with schizophrenia, previously treated for 4 months with PP1M. PP3M was tolerable with a safety profile generally consistent with other marketed formulations of paliperidone.