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LONG-TERM SAFETY, TOLERABILITY AND PHARMACOKINETICS OF PALIPERIDONE PALMITATE: A ONE-YEAR OPEN-LABEL STUDY IN PATIENTS WITH SCHIZOPHRENIA

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Abstract:

AIMS

To evaluate the pharmacokinetics (PK), and long-term safety and tolerability of the highest marketed dose of paliperidone palmitate (PP; 234 mg [150 mg eq.]) in stable patients with schizophrenia.

METHODS

In this 1-yr open-label study, eligible patients (PANSS total score ≤70; aged 19-65 yrs) received an initial deltoid injection of 234 mg PP. The second injection of PP a wk later and subsequent once-monthly injections were deltoid or gluteal. Patients on 234 mg PP willing to participate in intensive PK sampling were classified as Group A. Patients unwilling to undergo intensive PK sampling or unable to tolerate the 234 mg dose (consequently receiving flexible doses of 78, 156 or 234 mg) were classified as Group B.

RESULTS

Of the 212 patients (safety analysis set), 73% were men; 45% White, 34% Asians, 20% Black, mean (SD) age 41 (10.2) yrs, and mean (SD) baseline PANSS total score 54.9 (9.03). 113 patients completed the study; 104 received 234 mg PP throughout. 55% of patients received deltoid injections exclusively. Mean (SD) dose of PP was 228 (20) mg. As a result of the initiation regimen used, therapeutic paliperidone levels were rapidly achieved and maintained (average concentrations during the dosing interval were 34.7, 40.0, and 47.7 ng/mL after the 2^{nd}, 8^{th}, 14^{th} injection respectively). Frequent TEAEs (≥5% of all patients) were nasopharyngitis (n=37), insomnia (n=32) and injection site pain (n=32). Akathisia (n=19) and tremor (n=11) were the most common treatment-emergent EPS-related AEs. 33 patients had a SAE and 27 patients discontinued due to TEAEs. No deaths were reported. The mean (SD) change from baseline in weight was 2.5 (5.41) kg at endpoint. Efficacy measures showed that patients' psychosis remained stable.

CONCLUSION

Safety results after long-term therapy with the highest available dose of once-monthly PP were consistent with results from previous studies. No new safety signals were noted. Plasma concentrations were within the expected range.

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