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FLEXIBLY DOSED PALIPERIDONE PALMITATE IN NON-ACUTE PATIENTS WITH SCHIZOPHRENIA SWITCHED FROM PREVIOUSLY UNSUCCESSFUL MONOTHERAPY WITH ORAL ATYPICAL ANTIPSYCHOTICS

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INTRODUCTION: To explore tolerability, safety and treatment response of flexibly dosed paliperidone palmitate (PP) in adult non-acute schizophrenia patients previously unsuccessfully treated with oral antipsychotic monotherapy of risperidone (RIS), paliperidone ER (Pali ER), olanzapine (OLA), quetiapine (QUE) or aripiprazole (ARI).

METHODS: International, prospective 6-month open-label study. Outcomes were response (≥20% improvement in Positive and Negative Syndrome Scale (PANSS) total score at endpoint), patient functioning (Personal and Social Performance scale (PSP)), treatment-emergent adverse events (TEAEs) and Extrapyramidal Symptom Rating Scale (ESRS).

RESULTS: Intent-to-treat population: n=191 (RIS), n=104 (Pali ER), n=87 (OLA), n=46 (ARI), n=44 (QUE). Patients presented some differences in baseline demographics, e.g. in age, years since diagnosis and BMI. Baseline mean PANSS total scores ranged from 74.7±14.9 (ARI) to 70.8±13.1 (QUE) and 70.8±15.1 (RIS). Between 67.4% (ARI) and 83.2% (RIS) of patients completed the study. At endpoint, 74% (RIS), 58% (Pali ER), 61% (OLA), 66% (QUE) and 52% (ARI) of patients had improved ≥20% in PANSS total score. Mean PSP improvement at endpoint was: 10.4±13.8 (RIS), 7.0±13.8 (Pali ER), 4.5±15.9 (OLA), 7.9±12.4 (QUE) and 3.9±13.2 (ARI); all $p<0.05$. TEAEs reported at least once in all subgroups were injection site pain, insomnia and psychotic disorder. Mean change in ESRS from baseline to endpoint was -1.2±3.5 (RIS), -0.7±4.1 (Pali ER), -1.3±4.4 (OLA), -0.3±3.2 (QUE) and -0.6±3.4 (ARI; $p<0.05$ for all except QUE).

CONCLUSION: PP was well tolerated and associated with clinically relevant treatment response in patients previously unsuccessfully treated with oral atypical antipsychotic monotherapy, regardless of the medication that was switched.

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