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**FLEXIBLY DOSED PALIPERIDONE PALMITATE IN NON-ACUTE PATIENTS WITH SCHIZOPHRENIA PREVIOUSLY UNSUCCESSFULLY TREATED WITH CONVENTIONAL DEPOT ANTIPSYCHOTICS**

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A. Schreiner<sup>1</sup>, L. Hargarter<sup>1</sup>, P.M. Llorca<sup>2</sup>, B. Cosar<sup>3</sup>, A. Petralia<sup>4</sup>, P. Bergmans<sup>5</sup>, P. Cherubin<sup>6</sup>

<sup>1</sup>EMA MAF, Janssen-Cilag GmbH, Neuss, Germany ; <sup>2</sup>Psychiatry, CHRU Clermont-Ferrand Hopital Gabriel Montpied, Clermont-Ferrand, France ; <sup>3</sup>Psychiatry, Gazi University medical Faculty, Ankara, Turkey ; <sup>4</sup>U.O.P.I of Psychiatry, A.O.U. Policlinico Vittorio Emanuele, Catania, Italy ; <sup>5</sup>Biostatistics & Reporting, Janssen Cilag Benelux, Tilburg, Netherlands ; <sup>6</sup>EMA MAF, Janssen Cilag France, Issy-les-Moulineaux, France

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**Introduction:** To explore tolerability, safety and treatment response of flexibly dosed paliperidone palmitate (PP) in adult non-acute patients with schizophrenia previously unsuccessfully treated with the decanoate of haloperidol (Hal), flupentixol (Fpt), fluphenazine (Flu) or zuclopenthixol (Zuc).

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

**RESULTS:** The intent-to-treat population comprised n=53 Hal, n=35 Fpt, n=44 Flu and n=42 Zuc patients. Mean age ranged from 42.1 $\pm$ 10.7 [Zuc] to 44.4 $\pm$ 9.4 years [Hal], male gender from 57.1% [Zuc] to 69.8% [Hal], and BMI from 27.3 $\pm$ 5.9 [Hal] to 30.8 $\pm$ 8.5 kg/m<sup>2</sup> [Zuc]. Between 70.5% [Flu] and 85.7% [Fpt] of patients completed the study. Mean baseline PANSS total scores ranged from 73.7 $\pm$ 14.1 [Fpt] to 75.7 $\pm$ 13.2 [Hal] and decreased significantly by -7.5 $\pm$ 19.4 [Flu] to -10.6 $\pm$ 21.5 points [Zuc] at endpoint ( $p < 0.003$  all subgroups). At endpoint, between 53.7% [Zuc] to 61.8% [Fpt] of patients had improved  $\geq 20\%$  in PANSS total score. Patient functioning (PSP) improved by 5.2 $\pm$ 13.0 [Hal] to 6.4 $\pm$ 15.2 points [Zuc] (all  $p \leq 0.0071$ ). TEAEs reported at least once in all and in  $\geq 5\%$  in any subgroup were insomnia (max 11.5%), psychotic disorder (max 9.5%) and injection site pain (max 9.1% of subjects). Extrapyramidal symptoms in ESRS significantly improved from baseline to endpoint (all subgroups  $p < 0.01$ ).

**Conclusion:** Paliperidone palmitate was associated with a clinically meaningful treatment response and well tolerated in non-acute schizophrenia patients previously unsuccessfully treated with conventional depot antipsychotics.