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RISPERIDONE LONG-ACTING INJECTABLE IN STABLE PATIENTS WITH SCHIZOPHRENIA OR RELATED DISORDERS SWITCHED FROM ORAL OLANZAPINE

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Objective: To explore the efficacy of risperidone long-acting injectable (RLAI) in patients previously treated with oral olanzapine requiring therapy change.

Methods: This 6-month, multicenter, prospective, open-label trial evaluated adult patients with psychotic disorders treated with a stable dose of olanzapine, who required a treatment change due to lack of efficacy and/or tolerability. Three weeks after RLAI initiation, olanzapine use was tapered over 1 or 3 weeks at the discretion of the investigator. Primary efficacy evaluation was Positive and Negative Syndrome Scale (PANSS) total score change. Secondary endpoints included PANSS subscales, Clinical Global Impression-Severity (CGI-S), and Global Assessment of Functioning (GAF). Safety was evaluated by recording treatment-emergent adverse events (TEAEs).

Results: 96 patients were enrolled (53 tapered olanzapine within 1-week and 43 over 3-weeks). Mean olanzapine baseline dose was 19.2 ± 11.8 and 29.9 ± 17.5 mg/day in 1-week tapering and 3-week tapering groups, respectively. 40.6% of patients were initiated on 25 mg RLAI every-two-weeks. Treatment was completed by 79 patients (82.3%). Treatment discontinuation was mainly due to withdrawal of consent (n=4), AE (n=3), injection refusal (n=2), or lost to follow-up (n=2). Improvements in PANSS total and subscale scores, CGI-S and GAF were significant from baseline to endpoint ($p < 0.0001$). 74 TEAEs were reported in 42 patients (42.9%). TEAEs reported in $\geq 2\%$ of patients were agitation (3.6%), insomnia (3.6%), and schizophrenia (9.1%). Serious AEs occurred in 10 patients.

Conclusions: Switching treatment from oral olanzapine to RLAI led to clinically-relevant symptomatic and functional improvement in more than half of all patients. RLAI treatment was generally well-tolerated.