P03-359

RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY OF RISPERIDONE LONG-ACTING INJECTABLE IN RELAPSE PREVENTION IN PATIENTS WITH BIPOLAR I DISORDER

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Objectives: To evaluate risperidone long-acting injectable (RLAI) versus placebo in prevention of mood episodes in adults with bipolar I disorder.

Methods: A 12-week open-label period with RLAI (N=585) was followed by an 18-month randomized, double-blind period with RLAI (25, 37.5 or 50 mg/2 weeks; N=137) or placebo (N=140); a third group (N=138) was randomized to olanzapine for reference and exploratory comparisons. Primary efficacy endpoint: time to relapse of any mood episode for risperidone LAI vs. placebo in the double-blind period (Kaplan-Meier analysis). Relapse was defined by criteria including DSM diagnosis, further treatment, hospitalisation, or Clinical Global Impression score ≥4 combined with YMRS or MADRS >12.

Results: Dosing was fixed during the double-blind period at patients' final open-label dose (25 mg, 66%; 37.5 mg, 31%; 50 mg, 4%). Time to recurrence (any mood episode) was longer with RLAI versus placebo (log-rank test stratified by region and patient type, p=0.062; stratified by region only, p=0.032); the difference was significant for time to recurrence of elevated mood episodes (p=0.005) but not depressive episodes (p=0.587). Discontinuations due to adverse events (AEs) occurred in 2% of patients in the open-label period, and 4% and 1% in the RLAI and placebo groups, respectively, in the double-blind period. The most frequently reported AE in the open-label period was insomnia (15%). During double-blind treatment, the most frequently reported AEs with RLAI were weight increased (24%; placebo, 9%) and insomnia (16%; placebo, 17%).

Type of episode, n (%)	Risperidone LAI (N=135)	Placebo (N=138)
All mood episodes	52 (38.5)	77 (55.8)
Elevated mood episode	27 (20.0)	54 (39.1)
Hypomanic	2 (1.5)	4 (2.9)
Manic	17 (12.6)	43 (31.2)
Mixed	8 (5.9)	7 (5.1)
Depressive	25 (18.5)	23 (16.7)

[Table 1. Type of recurrence]

Conclusion: RLAI significantly delayed time to relapse of elevated mood episodes and was well tolerated.

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