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Remission in Lurasidone-treated Patients with Bipolar I Depression: Post-hoc Analysis of a 6-week, Placebo-controlled Trial Followed by a 6-month Extension

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Background

The objective of this post-hoc analysis was to evaluate recovery-related outcomes in patients with bipolar depression treated with lurasidone.

Methods

Subjects meeting DSM-IV-TR criteria for bipolar I depression, with or without rapid cycling, were randomized to 6 weeks of once-daily, double-blind treatment with either lurasidone 20-60 mg (LUR20-60), lurasidone 80-120 mg (LUR80-120) or placebo (PBO), followed by a 6-month, open-label, continuation study of lurasidone.

Results

At end of the 6-week acute phase, a significantly higher proportion of subjects met both symptomatic (MADRS total score $\leq$ 12) and functional (mean SDS total score $\leq$ 3 and all SDS domain scores $\leq$ 3 for mildly impairment) remission criteria in the lurasidone group (33%,N=273 pooling the LUR20-60 and LUR80-120 groups) compared to the placebo group (15%, N=143,$p<0.05$, NNT = 6). In the 6-month continuation study, the proportion of subjects achieving symptomatic and functional remission at both week 19 and week 32 (month 3 and month 6 of the continuation study, respectively) was 61% (85/140) in subjects who continued lurasidone treatment (LUR-LUR) and 45% (31/69) in subjects who switched from placebo to lurasidone (PBO-LUR). Multivariate logistic modeling revealed that statistically significant predictors of symptomatic and functional recovery included: lower baseline symptom severity, non-white race, and taking lurasidone (rather than placebo) during the acute phase.

Discussion

Our findings support the potential for attainment of remission in patients with bipolar I depression treated with lurasidone, which might lead to clinical and functional recovery.

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