

readmission among youths with BD. Randomized trial of family-focused therapy was used to determine early interventions for symptomatic teenagers at risk for BD.

Keywords: interventions, adolescents, compliance, bipolar, decrease in hospitalization

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Open-label Study of Pimavanserin Patients with Comorbid Parkinson's Disease and Depression

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ABSTRACT: Study Objectives: Depression occurs in ~50% of Parkinson's disease (PD) patients, increases in severity and duration as the disease progresses, and is associated with increased morbidity. Improvement of depression in PD patients is correlated with reduced physical disability and improved quality of life. We are assessing use of pimavanserin (PIM) for treatment of depression in adults with PD.

METHOD: A Phase-2, 8-week, open-label, single-arm study is being conducted to evaluate the safety and efficacy of PIM as an adjunct to SSRI/SNRI or as monotherapy in adults with both PD and symptoms of depression (baseline Hamilton Depression Scale [17-items] total score [HAMD-17] ≥ 15). The primary endpoint of the study is change from Baseline to Week 8 in the HAMD-17. Secondary measures included the Clinical Global Impression (CGI) scales (improvement and severity) and Scales of Outcomes in PD-Sleep (SCOPA).

RESULTS: Interim results based on the first 34 of 40 planned patients have been evaluated: 55.9% of patients were male, and average age was 68.1 years, with 19 patients on adjunctive therapy and 15 on monotherapy. At baseline, patients had a mean (SE) HAMD-17 of 19.8(0.6). Change from Baseline to Week 8 (least squares

mean [LSM] [SE]) in the HAMD-17 was -10.7(1.0) (95% CI; -12.7,-8.7; $P < 0.001$), with significant improvement seen as early as Week 2 (-8.4[1.0]; 95% CI; -10.5,-6.4; $P < 0.001$). Significant improvement was seen for both adjunctive treatment and monotherapy: 45.2% of patients responded to treatment ($\geq 50\%$ improvement on the HAMD-17) at Week 8, and 35.5% reached remission (HAMD-17 ≤ 7). On the Clinical Global Impressions-Improvement scale, 54.8% were much/very much improved at Week 8. Significant improvement was seen in change from Baseline to Week 8 SCOPA-Global Sleep Quality, -Nighttime Sleep, and -Daytime Sleepiness: -1.0(0.4) (95% CI; -1.7,-0.3; $P = 0.010$), -2.1(0.7) (95% CI; -3.6,-0.6; $P = 0.008$), -2.1(0.4) (95% CI; -3.0,-1.2; $P < 0.001$) respectively. Twenty-one of the 34 enrolled patients have completed the study to date, and another 7 are still continuing. Thirteen patients reported adverse events, the most common being falls, UTI, diarrhea, and nausea.

CONCLUSIONS: These interim data suggest that PIM as adjunctive treatment or monotherapy is associated with early improvement of depressive symptoms in patients with PD and is well tolerated. This is consistent with recently reported data of PIM in major depressive disorder. Final data will be shared at the time of this presentation. However, additional placebo-controlled data will be needed to determine fully the efficacy of PIM in patients with comorbid PD and depression.
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Safety and Efficacy of Lurasidone in Children and Adolescents with Bipolar Depression: Results from a 2-Year Open-label Extension Study

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ABSTRACT: Background: Bipolar I disorder frequently has an early onset, with an estimated prevalence rate of 1.8% in pediatric populations. Early onset is associated with a high degree of chronicity; however, limited data are available on the long-term efficacy of drug therapies in pediatric populations. The aim of the current study was to evaluate the long-term safety and efficacy of lurasidone in children and adolescents with bipolar depression.