P01-69 - **LONG-TERM ASENAPINE TREATMENT FOR BIPOLAR DISORDER: A DOUBLE-BLIND 40-WEEK EXTENSION STUDY**

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Objectives: Asenapine is indicated in adults for acute treatment of schizophrenia and manic or mixed episodes associated with bipolar I disorder with or without psychotic features. We report the safety, tolerability, and efficacy of asenapine in patients with bipolar I disorder completing up to 52 weeks of treatment.

Methods: Patients completing either of two 3-week efficacy trials and a 9-week double-blind extension were eligible for this 40-week double-blind extension. Patients in the 3-week trials were randomized to flexible-dose asenapine (5 or 10 mg BID), placebo, or olanzapine (5-20 mg QD; included for assay sensitivity only). Patients entering the extension continued their preestablished treatment; those originally randomized to placebo received flexible-dose asenapine (placebo/asenapine, 5 or 10 mg BID). Safety and tolerability endpoints included adverse events (AEs), extrapyramidal symptoms, laboratory values, and anthropometric measures. Efficacy was measured as the change in Young Mania Rating Scale (YMRS) total score from 3-week trial baseline to week 52; the placebo/asenapine group was included in the safety analyses.

Results: Incidence of treatment-emergent AEs was 71.9%, 86.1%, and 79.4% with placebo/asenapine, asenapine, and olanzapine, respectively. The most frequent AEs included headache and somnolence (placebo/asenapine); insomnia, sedation, and depression (asenapine); and weight gain, somnolence, and sedation (olanzapine). Mean ± SD changes in YMRS score at week 52 among observed cases in the intent-to-treat population were -28.6±8.1 for asenapine and -28.2±6.8 for olanzapine.

Conclusions: In this 52-week study, asenapine was well tolerated and long-term maintenance of efficacy was supported in patients initially presenting with bipolar mania.

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