PW01-28 - **ASENAPINE AS ADJUNCTIVE TREATMENT FOR BIPOLAR MANIA: A PLACEBO-CONTROLLED 12-WEEK STUDY AND 40-WEEK EXTENSION**

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Objectives: Asenapine is indicated in adults for acute treatment of schizophrenia and bipolar I disorder. We describe the efficacy and tolerability of adjunctive asenapine in bipolar patients showing incomplete response to lithium or valproate monotherapy.

Methods: In a 12-week core study, patients were randomized to flexible-dose asenapine (5 or 10 mg BID) or placebo as an adjunct to continued mood stabilizer therapy. Patients completing the core study without protocol violations could enter a 40-week extension. Changes from core study baseline on the Young Mania Rating Scale (YMRS) and Montgomery-Asberg Depression Rating Scale (MADRS) total scores were assessed at week 3 of the core study and at week 52 in the extension. Efficacy in the core study was assessed using ANCOVA with LOCF to impute missing data. The extension was not powered for statistical comparisons; descriptive statistics were employed.

Results: The intent-to-treat population comprised 318 patients (asenapine, 155; placebo, 163) in the core study and 71 (38; 33) in the extension. Mean±SD changes at week 3 with asenapine and placebo, respectively, were -9.7±10.1 versus -7.7±9.6 (P=0.0257) on YMRS and -2.8±7.2 versus -2.2±6.8 (P=0.3684) on MADRS. Mean±SD changes at week 52 with asenapine and placebo were -17.2±13.7 versus -19.7±11.8 on YMRS and -3.3±9.8 versus -3.9±7.7 on MADRS. The incidence of treatment-emergent AEs with asenapine and placebo was 73% and 69% in the core study, 78% and 69% in the extension.

Conclusions: Asenapine was effective as an adjunct to mood stabilizer in bipolar I disorder and was well tolerated.

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