

The Efficacy of Asenapine in the Treatment of Bipolar Disorder: a Naturalistic Longitudinal Study Indicating a Favourable Response in Patients with Substance Abuse Comorbidity

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Abstract. Introduction. Asenapine is a second-generation antipsychotic approved in Europe for the treatment of moderate to severe manic episodes in adults affected by Bipolar Disorder I (BD I). **Aims.** We aimed to assess the efficacy of asenapine in controlling manic, mixed and/or depressive symptoms in an inpatient psychiatric population. **Methods.** A total of 119 voluntarily hospitalised patients with DSM-IV-TR BD I diagnosis received flexible asenapine doses ranging 5 to 20 mg/day. Patients were assessed with clinician-rated questionnaires, i.e., Brief Psychiatric Rating Scale (BPRS), Young Mania Rating Scale (YMRS), Hamilton Depression Rating Scale (HAM-D), Hamilton Anxiety Rating Scale (HAM-A), and Global Assessment of Functioning (GAF). Assessment was carried-out at baseline (T0, prior to treatment), and three (T1), seven (T2), 15 (T3), and 30 days (T4) after starting treatment for all clinical scales and at T0 and T4 for the GAF. **Results.** Patients improved on all scales ($p < .001$) across time-points, as shown both by paired-sample comparisons and by applying a repeated-measures, generalized linear model (GLM). Substance abuse was associated with greater reductions in anxious-depressive scores. Side effects were few and not severe. **Conclusion.** Asenapine showed effectiveness and safety in a hospitalised bipolar I population. Its effect was greater in the presence of substance abuse.