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META-ANALYSES OF THE EFFICACY OF ASENAPINE VS PLACEBO IN BIPOLAR I DISORDER AS MONOTHERAPY AND ADJUNCT THERAPY COMPARED WITH OTHER ATYPICAL ANTIPSYCHOTICS

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Introduction: Superiority of asenapine vs placebo, as monotherapy or adjunctive therapy to lithium or valproate, for acute bipolar mania has previously been reported.

Objective: Present meta-analyses of asenapine compared with atypical antipsychotics based on placebo-controlled trials.

Aim: Further demonstrate the efficacy of asenapine for acute bipolar mania.

Methods: The primary endpoint was change from baseline vs placebo on Young Mania Rating Scale (YMRS) total score at treatment week 3. Data for asenapine (5 or 10 mg BID) and comparators were obtained from all monotherapy (n=20) or adjunctive treatment trials in patients showing incomplete response to lithium or valproate monotherapy (n=10) published at the time of the analysis. Meta-analyses used a random-effects model described by DerSimonian and Laird (Control Clin Trials 1986;7:177-188).

Results: Treatment effects varied substantially across agents and for individual agents across trials. For monotherapy, the change from baseline in YMRS total score with asenapine exceeded placebo by 4.5 points (95% CI, 2.5-6.4; $p < 0.0001$); this was comparable to the treatment effect of all comparators vs placebo (4.9 points; 95% CI, 3.8-6.0). The treatment effect for adjunctive asenapine exceeded placebo by 2.4 points (95% CI, 0.5-4.3); this was also comparable to the overall treatment effect for the combined comparators (2.7 points; 95% CI, 2.0-3.3).

Discussion: These meta-analyses demonstrate statistical superiority of asenapine over placebo, as monotherapy or adjunctive therapy, for acute bipolar mania. Further, they reveal that the efficacy of asenapine is similar to that of other atypical antipsychotics used as monotherapy or adjunctive therapy.