

P-214 - INCIDENCE, ONSET AND DURATION OF TREATMENT-EMERGENT SOMNOLENCE WITH ASENAPINE IN PATIENTS WITH SCHIZOPHRENIA OR BIPOLAR DISORDER

P.Cazorla, , J.Zhao, A.Szegedi

Merck, Whitehouse Station, NJ, USA

Introduction & objective: Assess the incidence and time-course of somnolence in placebo- and active-controlled asenapine schizophrenia and bipolar I disorder (BD) trials.

Methods: Data were from schizophrenia (4 short-term [6wk]; 3 long-term [26-52wk]) and BD (2 short-term [3wk]; one 12-wk adjunct therapy to mood stabilizers) trials. Data were pooled across asenapine doses (5or10mg BID); active controls were risperidone 3mg BID, olanzapine 5-20mg QD, and haloperidol 4mg BID.

Results: For schizophrenia, incidence of somnolence was higher with active treatment than placebo in short-term trials; (asenapine,13.1%; placebo, 6.9%; active controls, 5-20%); and comparable for asenapine and olanzapine in long-term trials; (asenapine,18.4-18.5%; olanzapine, 19.6-21.1%); severe somnolence was infrequent (0-8%). Somnolence onset (median [days]) occurred early in short-term (asenapine, 2.0; placebo, 7.0; active controls, 2-6) and long-term (asenapine, 9.0; olanzapine, 7.5-9.0) trials; median somnolence duration (days) was relatively brief in short-term (asenapine,15.0; placebo, 4.5; active controls; 3.0-22.5) and long-term (asenapine, 22.0-25.0; olanzapine, 21.0-25.0) trials. For BD, incidence of somnolence was higher with active treatment than placebo in short-term (asenapine, 23.8%; placebo, 6.4%; olanzapine, 26.4%) and adjunctive therapy (asenapine, 24.1%; placebo, 10.2%) trials; severe somnolence was infrequent (0-3%). Somnolence onset (median [days]) occurred early in short-term (asenapine, 1.0; placebo, 2.0; olanzapine, 1.0) and adjunctive therapy (asenapine,1.5; placebo,2.0) trials; median somnolence duration (days) was brief in short-term (asenapine, 7.0; placebo, 5.0; olanzapine, 8.5) and adjunctive therapy (asenapine,12.5; placebo, 7.0) trials.

Conclusions: The analyses show, on average, an early onset and a limited duration of treatment-emergent somnolence with asenapine, which may be clinically useful in certain clinical situations.