P03-340

A POOLED ANALYSIS OF THE EFFECTS OF ASENAPINE ON THE PERSISTENT NEGATIVE SYMPTOMS OF SCHIZOPHRENIA

S.G. Potkin[1], P. Phiri[2], J. Zhao[2], L. Alphs[3], R.W. Buchanan[4], A. Szegedi[2], J. Panagides[5], P. Cazorla[2]

[1]University of California, Irvine, CA, [2]Merck, Rahway, NJ, [3]Pfizer Inc, at the the Time of this Research, Ann Arbor, MI, [4]Maryland Psychiatric Research Center, Baltimore, MD, [5]Merck, at the Time of this Research, Rahway, NJ, USA

Introduction: Asenapine and olanzapine reduced persistent negative symptoms (PNS) of schizophrenia in 2 double-blind, randomized 26-week studies and subsequent 26-week extensions; superiority of asenapine over olanzapine was observed in neither core study and only 1 extension.

Objective: Further explore the efficacy of asenapine on PNS using pooled data.

Aim: Demonstrate superiority of asenapine over olanzapine on PNS.

Methods: Core study participants were randomized to twice-daily asenapine 5 or 10 mg or once-daily olanzapine 5-20 mg; extension participants continued existing treatment. Changes from core study 16-item Negative Symptom Assessment (NSA-16) Scale baseline at Weeks 26 and 52 were estimated using MMRM.

Results: Of 949 treated participants (asenapine, 485; olanzapine, 464), 613 (277; 336) completed the core studies and 412 (170; 242) completed the extensions. Discontinuation due to lack of therapeutic effect was significantly greater with asenapine vs olanzapine for the first 26 weeks (13.6% vs 7.3%, p=0.0016) and during the extension (5.5% vs 2.1%, p=0.0458) for core and extension study participants, respectively. Between-group differences in least squares mean ± SE NSA-16 score change from core study baseline were significantly greater with asenapine at Week 52 for core (-14.6±0.8 vs -12.6±0.7; p=0.0497) and extension (-16.5±0.9 vs -13.6±0.7; p=0.0083) participants, but were not significant at Week 26.

Conclusions: In pooled analyses, asenapine and olanzapine reduced PNS, with statistical superiority of asenapine observed at Week 52 but not Week 26. These results should be interpreted in view of the fact that participants who entered the extensions did so without rerandomization.

https://doi.org/10.1016/S0924-9338(11)73214-X Published online by Cambridge University Press