P01-249

WEIGHT CHANGE AND METABOLIC EFFECTS OF ASENAPINE IN PLACEBO- OR OLANZAPINE-CONTROLLED STUDIES

J. Zhao¹, P. Cazorla¹, J. Schoemaker², M. Mackle¹, J. Panagides³, C. Karson¹, A. Szegedi¹ Merck, Rahway, NJ, USA, ²MSD, Oss, The Netherlands, ³Merck, at the Time of this Research, Rahway, NJ, USA

Introduction: Weight change and metabolic effects of atypical antipsychotics vary considerably.

Objective: Assess weight and metabolic effects of asenapine in adults.

Aim: Demonstrate that asenapine marketed doses are well tolerated compared with placebo or olanzapine.

Methods: Data were from pooled asenapine trials that used placebo (1748 patients; duration: 1–6 wk) and/or olanzapine (3430 patients; duration, 3–>100 wk) controls. Asenapine doses were 5 or 10 mg BID (2-20 mg BID in 2 studies); olanzapine doses were 5-20 mg QD. Post hoc inferential analyses based on ANOVA assessed change from baseline weight, body mass index, and fasting lipid and glucose levels.

Results: Table 1 summarizes the results.

	Placebo-Controlled		Olanzapine-Controlled	
LS Mean±SE Change From Baseline	Asenapine n=989	Placebo n=759	Asenapine n=2067	Olanzapine n=1363
Weight, kg	1.2±0.2 [‡]	0.1±0.2	0.9±0.1 [‡]	3.1±0.2
BMI, kg/m ²	0.4±0.1 [‡]	0.0±0.1	0.3±0.1 [‡]	1.1±0.1
Total cholesterol, mg/dL	-1.2±3.6	-3.4±3.4	-0.4±1.1 [‡]	6.2±1.2
LDL, mg/dL	−0.4±1.1	-0.7±1.3	−0.3±1.1 [*]	3.1±1.2
HDL, mg/dL	0.3±0.4	0.2±0.4	1.3±0.4 [†]	-0.2±0.4
Fasting triglycerides, mg/dL	1.8±6.3 [*]	-12.2±5.9	-0.9±5.4 [‡]	24.3±5.8
Fasting glucose, mg/dL	1.9±1.7 [*]	-1.6±1.5	2.0±1.3	3.3±1.3

BMI=body mass index; HDL=high-density lipoprotein; LDL=low-density lipoprotein; LS=least squares. *P<0.05; †P<0.01; ‡P<0.0001 for asenapine vs comparator.

[Change From Baseline Weight and Metabolic Paramete]

Discussion: These post hoc pooled analyses support published reports and suggest asenapine was associated with moderate weight gain and increased fasting triglyceride and glucose levels vs placebo, but lower propensity for weight gain or increased serum lipids (ie, triglycerides, low-density lipoprotein, and cholesterol) vs olanzapine.