PW01-193 - **SAFETY AND EFFICACY OF LONG-TERM ASENAPINE VERSUS OLANZAPINE IN SCHIZOPHRENIA OR SCHIZOAFFECTIVE DISORDER PATIENTS**

J. Schoemaker[1], D. Naber[2], W. Jansen[1], J. Panagides[3], R. Emsley[4]

[1]Schering Corp., a Division of Merck & Co., Oss, The Netherlands, [2]University of Hamburg-Eppendorf, Hamburg, Germany, [3]Schering Corp., a Division of Merck & Co., Summit, NJ, USA, [4]University of Stellenbosch, Cape Town, South Africa

Objectives: Asenapine is indicated in adults for acute treatment of schizophrenia and bipolar I disorder. Here, the long-term safety and efficacy of asenapine versus olanzapine is described in schizophrenia and schizoaffective disorder patients treated for up to 3 years.

Methods: In a 1-year core study, patients were randomized to double-blind treatment with asenapine (5 or 10 mg BID) or olanzapine (10-20 mg QD). Patients completing the core study, and willing to continue treatment, received up to an additional 2 years of double-blind treatment. Safety evaluations assessments included adverse events (AEs), vital signs, body weight, and extrapyramidal symptoms (EPS). Efficacy, changes in Positive and Negative Syndrome Scale (PANSS) total score, was evaluated in the intent-to-treat population using observed cases.

Results: In 440 enrolled patients (asenapine, 290; olanzapine, 150), the mean±SD daily dose was 13.4±4.1 mg for both asenapine and olanzapine; total exposure duration (including core study exposure) was 676.3±148.1 and 692.5±140.7 days for asenapine and olanzapine, respectively. Mean weight gain was 1.6 kg with asenapine and 5.0 kg with olanzapine; incidence of clinically significant weight gain was 28% and 40%, respectively. Incidence of EPS-related AEs was 4.5% with asenapine and 3.3% with olanzapine. AEs occurring in ≥10% of patients treated for up to 3 years will be listed. Mean±SD changes in PANSS total score over the course of the extension study were 1.7±11.0 with asenapine and -0.8±9.5 with olanzapine.

Conclusions: Asenapine and olanzapine were well tolerated and maintained efficacy in patients receiving up to 3 years of treatment.

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