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Chicago, États-Unis (2 – 4 octobre 2008)

Eplivanserin, a novel sleep agent, improves sleep continuity without next-day effects in patients with chronic primary insomnia

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Introduction/hypothesis: We evaluated the effects of the novel Antagonist of Serotonin Two A Receptors (ASTAR), eplivanserin (EPL) on patients with chronic primary insomnia.

Methods: This was a multicenter, double-blind, placebo (PBO)-controlled, three-parallel-arm, 4-week study in 351 patients with a wake time after sleep onset (WASO) ≥ 30 min, problems with sleep onset latency (SOL) or non-restorative sleep ≥ 1 x/month. Patients were randomized to nightly PBO or EPL 1 or 5 mg. Patient-reported sleep parameters were recorded with morning sleep questionnaires assessing sleep quality (SQ), SOL, WASO, number of nighttime awakenings (NAW) and total sleep time (TST). Impression of treatment was measured on the Patient Global Impression scale. Adverse events (AEs) and next-day effects were assessed throughout, with rebound insomnia evaluated during a 1-week run-out.

Results: EPL 5 mg significantly reduced WASO vs PBO ($-38:37$ vs $-26:08$ min:sec; $P=0.009$), and both EPL 1 and 5 mg significantly reduced NAW vs PBO (-2.2 and -1.0 vs -1.0 ; $P=0.025$ and 0.008 , respectively). EPL 5 mg improved refreshing SQ (-0.5 vs -0.4 ; $P=0.049$; 4-point Likert scale) and there was a trend of increased TST vs PBO ($+42:45$ vs $+30:12$ min:sec; $P=0.072$), with more EPL 5 mg- than PBO-treated patients reporting that the study drug aided sleep (64% vs 52%; $P=0.076$). Neither EPL 1 nor 5 mg significantly affected SQ (primary endpoint) or SOL vs PBO. Treatment-emergent AEs $\geq 5\%$ with EPL 1 and 5 mg vs PBO were headache (9.4 and 12.3 vs 9.2%), dry mouth (2.6 and 5.3 vs 1.7%) and dizziness (5.1 and 1.8 vs 2.5%). There were no serious AEs or next-day residual effects (morning sleepiness/ability to concentrate), and there was no evidence of rebound insomnia after EPL discontinuation.

Conclusion: EPL 5 mg/day improved sleep continuity by decreasing WASO and NAW in insomnia patients and was well tolerated, with no effect on next-day functioning or rebound insomnia. This study was funded by sanofi-aventis, Inc.