ALTASCIENCES

CASE STUDY

Driving Simulator Assessment

The study drug was a centrally acting, multifunctional serotonin agonist/antagonist that was developed for the treatment of hypoactive sexual desire disorder (HSDD) in premenopausal women. To achieve therapeutic efficiency and minimize the most common adverse effects (AEs) reported after dosing—which include dizziness (11.4%), somnolence (11.2%), nausea (10.4%) and fatigue (9.2%)—chronic bedtime oral dosing was necessary to ensure these AEs would not affect the ability to drive in the morning,

Altasciences conducted novel endpoint research to determine the extent of next-day impairment in cognition and alertness.

A randomized, double-blind, placebo-controlled, four-way crossover study was performed to evaluate the potential next-morning residual effects after bedtime dosing in 72 healthy premenopausal women. Treatment arms included a placebo administration group (acute and chronic), positive control zopiclone group (7.5 mg qhs; acute only), and two separate dosage groups of CNS study drug, which included 100 mg qhs (acute and chronic) or 200 mg qhs (acute after 100 mg chronic). Assessments were based on simulated driving, a Symbol Digit Coding Test (SDCT), and the Karolinska Sleepiness Scale (KSS).

Preliminary evaluation of next-day impairment during simulated driving revealed bedtime administration of the study drug, up to 200 mg did not impair next-day cognitive function or driving performance, while improving symptoms of HSDD. Women dosed with 100 mg qhs of the study drug before bed were found to have significantly ($p<0.01$) lower standard deviation of lateral position (SDLP) values compared to acute and chronically dosed placebo groups. No statistically significant differences were found between the 100 mg and 200 mg dose groups.

Altasciences was able to demonstrate that there was no impairment to driving the morning after nighttime dosing of the CNS study drug in premenopausal women. The study was described as “reassuring” by the FDA.

ABOUT ALTASCIENCES

Altasciences is an integrated drug development solution company offering pharmaceutical and biotechnology companies a proven, flexible approach to preclinical and clinical pharmacology studies, including formulation, manufacturing, and analytical services. For over 25 years, Altasciences has been partnering with sponsors to help support educated, faster, and more complete early drug development decisions. Altasciences’ integrated, full-service solutions include preclinical safety testing, clinical pharmacology and proof of concept, bioanalysis, program management, medical writing, biostatistics, clinical monitoring, and data management, all customizable to specific sponsor requirements. Altasciences helps sponsors get better drugs to the people who need them, faster.

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