

New Data Show Improvements in Work Performance in Patients with Chronic Insomnia Treated with AMBIEN CR® (zolpidem tartrate extended-release) tablets C_{IV}

Study Confirms Role of AMBIEN CR in Effectively Managing Insomnia to Improve Quantity and Quality of Work Performance

Bridgewater, NJ – October 24, 2007 – Sanofi-aventis today announced results from a new study that showed patients with chronic insomnia who were treated with 12.5 mg of AMBIEN CR® (zolpidem tartrate extended-release) tablets C_{IV} experienced significant improvements in two key parameters of work performance – output and time management – over a period of 12 weeks compared with patients taking placebo. Patients with chronic insomnia can have a higher frequency of work-related problems including absenteeism, an increased rate of accidents, difficulty performing duties and less job satisfaction. These results, which were part of a larger study that evaluated the efficacy and safety of AMBIEN CR when taken as needed, were recently presented at the 20th Annual U.S. Psychiatric and Mental Health Congress in Orlando, Florida.

The multi-center, phase IIIb, randomized, double-blind study included 728 patients with chronic primary insomnia (478 treated with AMBIEN CR and 250 treated with placebo). Treatment with AMBIEN CR showed significantly higher improvement from baseline in work tasks at week 12 in Work Limitation Questionnaire (WLQ) for both Time Management Scale (- 7.39 difference; $p < 0.001$) and the Output Scale (- 4.8 difference; $p = 0.0076$) compared to placebo, which was confirmed by an effect size analysis. The majority of adverse events experienced by patients in the study were mild to moderate in intensity, and the most frequently reported adverse events by participants include headache, anxiety and somnolence.

“These new data add to the growing body of evidence that shows that the treatment of chronic insomnia can improve next day functioning,” said Milton Erman, MD, chief medical officer, Avastra USA, and clinical professor of psychiatry, UCSD School of Medicine. “This study demonstrates that AMBIEN CR is not only an effective treatment option to help patients with chronic insomnia fall and stay asleep, but is also associated with significant improvements in work performance. In that the performance improvements were correlated with the clinical improvements, this analysis demonstrated that AMBIEN CR-treated patients did better at work because their sleep improved.”

About the Study

Treatments were administered from three to seven nights a week during a six-month period. Work outcomes were measured by the Work Limitation Questionnaire (WLQ), a self-administrated questionnaire measuring the degree to which health problems interfere with the ability to perform job roles. Patients were asked to rate their level of performance on 25 specific job demands by assigning scores ranging from 0 (limitations none of the time) to 100 (limitations all of the time). WLQ outcomes were assessed at baseline, week 4, 12, and end of treatment (week 24) or premature discontinuation. Two of the WLQ scales were included in the study: worker output and time management. Worker output assessed the ability to meet demands for quantity and quality of work while completing tasks in a timely manner. Time management assessed the ability to meet time demands and cope with scheduling pressures.

Study Results

In patients treated with AMBIEN CR, mean output scores improved by 14.1 points compared to 9.3 points for placebo. Mean time management scores improved by 17.8 points for AMBIEN CR-treated patients compared to 8.6 points for placebo. While both AMBIEN CR and placebo decreased work output and time management scores between baseline and week 12, the changes were significantly higher in AMBIEN CR compared to placebo. Performance improvements were clinically valid, as improvements in the WLQ scores for AMBIEN CR-treated patients were correlated with improvements in subjective scores from the same patients.

Safety analyses, conducted in patients who took at least one dose of treatment, found that treatment-emergent adverse events were reported in approximately 63% of AMBIEN CR treated patients compared to 50% of patients treated with placebo. Serious adverse events were reported in approximately 3% of study patients taking AMBIEN CR compared to approximately 2% of patients treated with placebo. These adverse events were not considered by the investigator to be related to the study treatment.

About Insomnia

Insomnia can be a serious medical condition characterized by difficulty falling asleep, waking up often during the night and having trouble going back to sleep, waking up too early in the morning and feeling tired upon waking. More than 30 million Americans are affected by chronic insomnia each year.

Patients with chronic insomnia report higher rates of absenteeism and demonstrate poor work efficiency compared to normal sleepers. Chronic and occasional insomniacs were both more likely to doze off during daytime activities or when bored, and to take naps than individuals who do not experience insomnia. Insomnia can lead to stress and reduced productivity, and thus may be costly to the workplace.

About AMBIEN CR

AMBIEN CR is the first and only dual-layer, extended-release prescription sleep medication indicated to help induce and maintain sleep with no significant decrease in next-day performance. AMBIEN CR is delivered in two stages. The first layer dissolves quickly to induce sleep. The second layer is released more gradually into the body to help provide more continuous sleep.

Important Safety Information

AMBIEN CR is a treatment option you and your healthcare provider can consider along with lifestyle changes and can be taken for as long as your provider recommends. Until you know how AMBIEN CR will affect you, you shouldn't drive or operate machinery. Be sure you're able to devote 7 to 8 hours to sleep before being active again. Sleepwalking, and eating or driving while not fully awake, with amnesia for the event, have been reported. If you experience any of these behaviors contact your provider immediately. In rare cases, sleep medicines may cause allergic reactions such as swelling of your tongue or throat, shortness of breath or more severe results. If you have an allergic reaction while using AMBIEN CR, contact your doctor immediately. Side effects may include next-day drowsiness, dizziness and headache. It's non-narcotic; however, like most sleep medicines, it has some risk of dependency. Don't take it with alcohol.

For full prescribing information, please visit www.AMBIENCR.com.

About sanofi-aventis

Sanofi-aventis, a leading global pharmaceutical company, discovers, develops and distributes therapeutic solutions to improve the lives of everyone. Sanofi-aventis is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

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