Ambien CR® (zolpidem tartrate extended-release) tablets CIV
Improved Chronic Insomnia in Patients with Co-Morbid Generalized Anxiety Disorder

Sanofi-aventis announced today results from a new study that showed Ambien CR® (zolpidem tartrate extended-release) tablets CIV provided improvement in sleep onset, sleep maintenance and total sleep time for patients with co-morbid chronic insomnia and generalized anxiety disorder (GAD) compared to placebo. Ambien CR® also improved sleep-related next-day functioning measures.

About the Study
This study was a multi-center, double-blind, parallel-group, randomized, placebo-controlled trial in 381 adults ages 21 to 64 with co-morbid chronic insomnia and GAD. The study evaluated the overall improvement of insomnia, as measured by total sleep time in patients treated with Ambien CR® and the antidepressant escitalopram (Lexapro®) compared to treatment with placebo and escitalopram. Patients received Ambien CR® 12.5 mg (n=191) or placebo (n=190) each night followed by 10 mg of escitalopram each day during the 8-week study, followed by a one-week period of escitalopram only. Treatment was well tolerated during the study and adverse events were similar between treatment groups.

“The anxiety experienced by patients with GAD can often lead to sleep problems such as difficulty falling asleep or staying asleep,” says Thomas Roth, PhD, director of the Sleep Disorders and Research Center at Henry Ford Hospital. “Data from this study show that Ambien CR® can be considered a treatment option for the insomnia in GAD to help them get the full night’s sleep they need to maintain their next-day functioning.”

Researchers assessed treatment efficacy during clinic visits at Weeks 1, 2, 4, 6 and 8 and through daily patient-reported Morning Sleep Questionnaires (MSQ). The MSQ measured the primary efficacy outcome of total sleep time in addition to measurements of sleep onset latency, wake time after sleep onset, number of awakenings, quality of sleep and sleep-related next-day functioning.

Ambien CR® Improved Sleep Quality and Sleep Impact on Daily Activities in GAD Patients
Total sleep time was increased in the Ambien CR® group throughout the study. At Week 8, patients reporting sleeping an average of 106 minutes more than baseline compared to placebo-treated patients who reported sleeping an average 68 minutes more (P<0.0001). On average, Ambien CR®-treated patients reported falling asleep sooner and exhibited improved sleep maintenance based upon fewer night-time awakenings and decreased wake time after sleep onset compared to placebo-treated patients (P<0.0001). At Week 8, the number of night-time awakenings decreased in the Ambien CR®/escitalopram group (-1.33 ±1.26) compared to the placebo/escitalopram group (-0.76 ±1.02), and time to sleep onset was reduced 55.1 (±67.3) minutes with Ambien CR® compared to a reduction of 26.8 (±58.7) minutes with placebo (P<0.0001). In addition, patients reported improvements in secondary measures relating to daytime functioning, including morning energy, morning concentration and sleep impact on daily activities.
Adverse events occurred in 76% of patients treated with Ambien CR®/escitalopram and 71% of the patients treated with placebo/escitalopram. The most frequent adverse events experienced by both treatment groups were nausea, dizziness and fatigue. These adverse events have been reported in previous studies of both Ambien CR® and escitalopram and are known to be part of the safety profile of both treatments. One patient in each treatment group experienced different serious adverse events.

About Insomnia
Insomnia can be a serious medical condition characterized by difficulty falling asleep, difficulty staying 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. About 10% of 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. Insomnia can lead to stress and reduced productivity, and thus may be costly to the workplace.

About Ambien CR® (zolpidem tartrate extended-release tablets) CIV
Ambien CR® is indicated for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance (as measured by wake time after sleep onset).

Important Safety Information
Ambien CR® is a treatment option you and your healthcare provider can consider along with lifestyle changes and can be taken 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 PARIS: SAN) and in New York (NYSE: SNY).

Forward-looking statements
This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include product development, product potential projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future events, operations, products and services, and statements regarding future performance. Forward-looking statements are generally identified by the words “expects,” “anticipates,” “believes,” “intends,” “estimates,” “plans” and similar expressions. Although sanofi-aventis’ management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of sanofi-aventis, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMEA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of such products candidates, the absence of guarantee that the products candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives as well as those discussed or identified in the public filings with the SEC and the AMF made by sanofi-aventis, including those listed under “Risk Factors” and “Cautionary Statement Regarding Forward-Looking Statements” in sanofi-aventis’ annual report on Form 20-F for the year ended December 31, 2006. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.
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