



Positive Results From Phase 2 Study of Qnexa in Obstructive Sleep Apnea Presented at Sleep Meeting

Qnexa Treatment Shown to Reduce Sleep Apnea Events, Improve Blood Pressure and Increase Mean Overnight Oxygen Saturation

MOUNTAIN VIEW, Calif., June 8, 2010 /PRNewswire via COMTEX News Network/ -- VIVUS, Inc. (Nasdaq: VVUS) today announced that data from a previously reported phase 2 study evaluating the safety and efficacy of the investigational drug Qnexa(R) for the treatment of obstructive sleep apnea (OSA) were presented at SLEEP 2010, the 24th Annual Meeting of the Associated Professional Sleep Societies (APSS). Data from the study entitled, "A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of Phentermine/Topiramate CR (VI-0521) for the Treatment of Obstructive Sleep Apnea/Hypopnea Syndrome in Obese Adults," were presented by David Winslow, MD, president, Kentucky Research Group, Chest Medicine Associates, P.S.C., Louisville and the study's principal investigator. The presentation marks the first time these results have been presented at a major medical meeting.

The study demonstrated statistically significant improvement in the apnea/hypopnea index (AHI), a measure of the severity of sleep apnea, in patients with OSA treated with Qnexa for 28 weeks. Qnexa-treated patients also experienced significant weight loss, reductions in both systolic and diastolic blood pressure, and reductions in respiratory disturbances and improvements in overnight blood oxygen levels. Qnexa treatment was well-tolerated. The most common side effects were dry mouth, altered taste and sinus infection.

"Obstructive sleep apnea is a serious condition associated with potentially deadly cardiovascular and metabolic events for the more than 18 million patients living with the disease. Unfortunately, there are no drug treatments available for the condition, and because current treatment options are limited to devices or surgery, patient compliance is low," stated David Winslow, MD. "These positive Qnexa data, from what is considered a sizable study for OSA, are exciting for those of us in the medical community treating obese patients with hypopnea syndrome. Particularly notable are the positive improvements achieved in mean oxygen saturation levels, which are difficult to accomplish and incredibly important. Patients would truly benefit from a safe and effective oral pharmacologic therapy for OSA, and I look forward to further exploring the potential of Qnexa."

OSA is a sleep-related breathing disorder that involves a decrease or complete cessation of airflow despite an ongoing effort to breathe. OSA is associated with an increased risk of hypertension, diabetes, stroke, sudden cardiac death and all-cause mortality. Sleep apnea is one of the leading co-morbidities associated with obesity, and research has shown that weight loss can improve OSA.

The phase 2 study (OB-204) was a single-center, randomized, double-blind, placebo-controlled parallel group trial including 45 obese men and women (BMI 30 to 40 kg/m², inclusive), 30 to 65 years of age. Patients enrolled were diagnosed with OSA based on an AHI greater-than or equal to 15 (moderate to severe) at baseline. In addition to receiving active or placebo drug, all patients were provided with a lifestyle modification program.

Highlights of the study include:

- Patients treated with Qnexa for 28 weeks had a nearly two-fold improvement in mean AHI compared with placebo
 - Qnexa treatment reduced the number of apnea/hypopnea events from a mean of 45.5 events per hour of sleep to 14.0 - compared to placebo patients with a reduction from a mean 43.5 events per hour of sleep to 27.0 (LS Mean, ITT-LOCF p=0.0084 active vs. placebo).
- Qnexa treated patients lost 10.3% body weight, or 23.7 lbs, in 28 weeks, compared to 4.2% for placebo patients, or 10.4 lbs (LS Mean ITT-LOCF p<0.001 active vs. placebo).
- Systolic blood pressure was reduced by 15 mm Hg in the Qnexa group from a mean of 138 mm Hg at baseline (LS Mean ITT-LOCF p=0.04).
- Diastolic blood pressure was reduced by 6.3 mm Hg in the Qnexa group from a mean of 87 mm Hg at baseline (LS Mean ITT-LOCF P=0.7991).
- Mean overnight oxygen saturation was significantly improved in Qnexa patients (p=0.014 active vs. placebo).
- Qnexa patients had a net reduction in the sleep arousals per hour of 19.5 versus an increase in sleep arousals of 21.2 for the placebo group.
- Qnexa patients also had improvement in sleep quality as measured by a reduction in the Pittsburgh Sleep Quality Index (PSQI) as compared to the placebo group p=0.0419.

- Overall study completion rate was 88.9%.
- Qnexa treatment was well-tolerated with no serious adverse events reported in the Qnexa arm. The most common treatment-emergent adverse events were dry mouth, altered taste, sinusitis, upper respiratory infections, nasopharyngitis, paresthesia, diarrhea and constipation. Most of these adverse events were mild or moderate in severity.

"A safe and effective treatment for obstructive sleep apnea would be valuable for the sleep physician community and for the millions of patients living with this dangerous and often undiagnosed disorder," stated Leland Wilson, chief executive officer of VIVUS. "These phase 2 data indicate that the substantial weight loss achieved with Qnexa can significantly improve sleep apnea as measured by the apnea/hypopnea index. Patients in the study had improvements in multiple secondary endpoints including improvements in their sleep quality. We are pleased that Dr. Winslow is sharing these exciting data with the sleep community at SLEEP 2010, and we look forward to working with the FDA to determine a regulatory path forward for this indication."

About the OB-204 Study

This phase 2 study (OB-204) was a single-center, randomized, double-blind, placebo-controlled parallel group trial including 45 obese men and women (BMI 30 to 40 kg/m² inclusive), 30 to 65 years of age with OSA (AHI greater-than or equal to 15 at baseline), who had not been treated with, or who were not compliant with continuous positive airway pressure (CPAP) within three months of screening. Patients were randomized to placebo or full-dose Qnexa. Patients underwent a four-week dose titration followed by 24 weeks of additional treatment. All patients were also provided with an intensive lifestyle modification program focusing on diet and exercise. Overnight polysomnography was performed at baseline, Week 8 and Week 28. The primary endpoint was the change in AHI between baseline and Week 28; secondary endpoints included weight loss, oxygen saturation and changes in blood pressure.

About Obstructive Sleep Apnea (OSA)

Obstructive sleep apnea (OSA) is a sleep-related breathing disorder that involves a decrease or complete halt in airflow despite an ongoing effort to breathe. It is a common yet serious disorder characterized by repeated pauses in breathing during the sleep cycle. Approximately 18 million Americans are afflicted with OSA, though an estimated 90% of patients remain undiagnosed or untreated. Studies have identified a causal relationship between OSA and a number of cardiovascular and metabolic diseases including hypertension, diabetes, stroke, congestive heart failure and sudden cardiac death. Patient compliance can be an issue in treating OSA and can limit the effectiveness of currently available treatments, which include lifestyle changes, continuous positive airway pressure (CPAP) devices and surgery.

About VIVUS

VIVUS is a biopharmaceutical company developing innovative, next-generation therapies to address unmet needs in obesity, sleep apnea, diabetes and sexual health. The company's lead product in clinical development, Qnexa, has completed phase 3 clinical trials for the treatment of obesity and an NDA has been filed and accepted by the FDA, with an action date of October 28, 2010. Qnexa is also in phase 2 clinical development for the treatment of type 2 diabetes and obstructive sleep apnea. In the area of sexual health, VIVUS is in phase 3 development with avanafil, a potentially best-in-class PDE5 inhibitor for the treatment of erectile dysfunction. MUSE(R) (alprostadil), a first generation therapy for the treatment of ED, is already on the market and generating revenue for VIVUS. For more information about the company, please visit www.vivus.com.

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimated" and "intend," among others. These forward-looking statements are based on VIVUS' current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, substantial competition; uncertainties of patent protection and litigation; uncertainties of government or third party payer reimbursement; reliance on sole source suppliers; limited sales and marketing efforts and dependence upon third parties; risks related to the development of innovative products; and risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. There are no guarantees that future clinical studies discussed in this press release will be completed or successful or that any product will receive regulatory approval for any indication or prove to be commercially successful. VIVUS does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in VIVUS' Form 10-K for the year ended December 31, 2009 and periodic reports filed with the Securities and Exchange Commission.

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