QNEXA® Phase 3 Data in The Lancet Show Significant Weight Loss and Broad Improvements in Co-Morbidities

Detailed CONQUER Results Demonstrate Overall Improvements in Cardiovascular and Metabolic Disease Risk Factors in Overweight/Obese Patients

MOUNTAIN VIEW, Calif., April 11, 2011 /PRNewswire/ -- VIVUS, Inc. (NASDAQ: VVUS) today announced that detailed results from the 56-week CONQUER study were published in *The Lancet* evaluating the efficacy and safety of investigational drug QNEXA in 2,487 patients across 93 sites in the US. Data published in the peer-reviewed journal provided an in-depth look at weight loss and improvements in the full spectrum of co-morbidities studied as secondary endpoints, including cardiovascular, metabolic and inflammatory risk factors.

"Obesity is a serious medical condition associated with increased mortality from cardiovascular diseases, diabetes, cancer and other diseases, yet there is a lack of treatment options for the one-third of American adults who are obese," said Kishore Gadde, MD, director of obesity clinical trials at Duke University and lead investigator. "Half the patients in the study had at least three co-morbidities including diabetes, representing a population with the greatest medical need for weight loss. We observed significant weight loss, improvements in co-morbidities and a reduction in the need for concomitant medications in patients treated with QNEXA."

Specific results for all patients through 56 weeks as published in *The Lancet* are as follows:

Weight Loss

- Average weight loss for QNEXA patients who completed the CONQUER study on the study drug was 28 pounds and 22 pounds with top-dose QNEXA and mid-dose QNEXA, respectively, compared to 4 pounds in the placebo group;
- In the ITT-LOCF analysis, least-squares mean percent weight loss at week 56 was -7.8%* and -9.8%*, respectively, for the mid and top dose as compared to -1.2% for the placebo group;
- Categorical weight loss from baseline (ITT-LOCF) was:

	≥5%	≥10%
Top dose	70%*	48%*
Mid dose	62%*	37%*
Placebo	21%	7%

*p<0.0001 vs placebo

Blood Pressure

- Reduction in systolic blood pressure of -4.7 mm Hg (p=0.0008) and -5.6 mm Hg (p<0.0001), respectively, for the mid and top dose as compared to -2.4 mm Hg for the placebo group;
- Reduction in diastolic blood pressure of -3.4 mm Hg (p=0.1281) and -3.8 mm Hg (p=0.0031), respectively, for the mid and top dose as compared to -2.7 mm Hg for the placebo group;
- More patients had a reduction in the number of blood pressure medications with QNEXA treatment compared to placebo.

Lipids

- Improvements in HDL cholesterol of 5.2% (p<0.0001) and 6.8% (p<0.0001), respectively, for the mid and top dose as compared to 1.2% for the placebo group;
- Reduction in LDL cholesterol of -3.7% (p=0.7391) and -6.9% (p=0.0069), respectively, for the mid and top dose as compared to -4.1% for the placebo group;
- Reduction in triglyceride levels of -8.6% (p<0.0001) and -10.6% (p<0.0001), respectively, for the mid and top dose as compared to an increase of 4.7% for the placebo group.

Metabolic Parameters

- Reduction in fasting insulin of -24.0 pmol/L (p=0.0004) and -27.6 pmol/L (p<0.0001), respectively, for the mid and top dose as compared to an increase of 5.1 pmol/L for the placebo group;
- Fewer non-diabetic patients on QNEXA progressed to type 2 diabetes; relative risk (vs placebo) was 0.47 (0.25 — 0.88) with top-dose QNEXA;
- More patients in the placebo group required an increase in the number of antidiabetic drugs than those treated with QNEXA.

More patients completed one year of treatment in the QNEXA groups, mid dose (69%) and top dose (64%) respectively, as compared to 57% in the placebo group. QNEXA therapy was well tolerated, with no unexpected adverse events. The most common side effects were dry mouth, paresthesia (tingling), constipation, insomnia, dizziness and dysgeusia (altered taste). Rates of serious adverse events were similar across treatment groups: 4% with placebo, 3% with mid-dose QNEXA and 5% with top-dose QNEXA. Most adverse events were seen early in treatment and there was a low dropout rate due to adverse events, 12% and 19% for mid and top dose respectively, compared to 9% for placebo.

About the CONQUER Study

The CONQUER study included 2,487 overweight and obese patients (1,737 females and 750 males) with high blood pressure, high cholesterol or type 2 diabetes across 93 centers in the United States. The average baseline BMI of the study population was 36.6 kg/m2 and baseline weight was 227 pounds. The study was a randomized, double-blind, placebo-controlled, 3-arm, prospective trial with patients randomized to receive once-a-day treatment with mid-dose QNEXA, top dose QNEXA or placebo. Patients had a 4-week dose titration period followed by 52 weeks of treatment. Throughout the 56-week treatment period, all patients were advised to follow a modest lifestyle modification program including reduction of food intake by 500 calories per day. Patients were actively managed to standard of care for weight-related co-morbidities, which included the ability for physicians to adjust or alter medications for these conditions, including in the placebo group.

About QNEXA Controlled-Release Capsules

QNEXA [kyoo-*nek*-suh] is an investigational drug candidate being developed to address weight loss, type 2 diabetes and obstructive sleep apnea. QNEXA is a once-a-day, proprietary, oral, controlled-release formulation of low-dose phentermine and topiramate, which is designed to decrease appetite and increase satiety (the sense of feeling full), the two main mechanisms that impact eating behavior. In phase 2 and 3 clinical data to date, patients taking QNEXA have demonstrated statistically significant weight loss, glycemic control, and improvement in cardiovascular risk factors, when used in combination with a diet and lifestyle modification program.

About VIVUS

VIVUS is a biopharmaceutical company developing therapies to address obesity, sleep apnea, diabetes and male sexual health. The company's lead product in clinical development, QNEXA, has completed phase 3 clinical trials for the treatment of obesity and is currently being considered for approval by US and EU regulators. 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 PDE5 inhibitor being studied for the treatment of erectile dysfunction. For more information about the company, please visit www.vivus.com

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