



VIVUS Announces Positive Results From Two Phase 3 Studies; Obese Patients on Qnexa Achieve Average Weight Loss up to 14.7% and Significant Improvements in Co-Morbidities

Results of EQUIP and CONQUER Phase 3 Studies Exceed FDA Benchmarks for Obesity Treatments, Demonstrate Positive Safety Profile

MOUNTAIN VIEW, Calif., Sept 09, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- VIVUS, Inc. (Nasdaq: VVUS) today announced positive results from two final, phase 3 pivotal 56-week studies, EQUIP (OB-302) and CONQUER (OB-303), evaluating the safety and efficacy of Qnexa(TM), an investigational drug, in more than 3,750 patients across 93 sites. The EQUIP and CONQUER studies met all primary endpoints by demonstrating statistically significant weight loss with all three doses of Qnexa, as compared to placebo. Patients taking Qnexa also achieved significant improvements in cardiovascular and metabolic risk factors including blood pressure, lipid levels, and type 2 diabetes.

Key Data

Highlights from the EQUIP and CONQUER studies include:

- Average weight loss of 14.7% (37 lbs) was achieved by patients treated with Qnexa for 56 weeks in the EQUIP study;
- Significant improvements in cardiovascular, metabolic and inflammatory risk factors among patients treated with Qnexa;
- FDA efficacy benchmarks for weight loss agents exceeded at all three doses of Qnexa tested in the clinical program;
- Completion rates up to 69% were significantly higher than placebo at all three doses of Qnexa, indicating favorable tolerability; and
- Favorable benefit/risk safety profile for Qnexa.

"The outstanding results from the EQUIP and CONQUER studies, in addition to the results from EQUATE that were reported late last year, confirm the positive effect of Qnexa and underscore the important role this therapy may play in the lives of patients battling obesity and related co-morbidities, if approved by the FDA," stated Leland Wilson, president and chief executive officer of VIVUS. "The results of the phase 3 program, designed and executed after Special Protocol Assessments were completed by the FDA, exceed the FDA benchmarks for clinically significant weight loss. The results support the company's plan to file a New Drug Application with the FDA by the end of 2009 and submit the results from the studies for publication in peer-reviewed journals. We believe these results may provide a compelling opportunity for global pharmaceutical companies, and we intend to initiate partnering discussions now that we have the full data set in hand."

Wilson added, "We are proud of the results of our Qnexa phase 3 program, and I would like to thank Dr. Thomas Najarian, the inventor of Qnexa, the entire development team at VIVUS, Dr. David Orloff and his staff at Medpace, the clinical research organization that managed these studies, and the clinical investigators and patients who participated in the Qnexa clinical trials."

Qnexa is a proprietary formulation and unique dosing regimen that combines two well known pharmaceutical therapies - phentermine and topiramate - to create a novel, patented therapy. The phase 3 program evaluated three doses of Qnexa (numbers reflect milligrams of phentermine and controlled release topiramate, respectively):

- Qnexa 15/92 (full dose)
- Qnexa 7.5/46 (mid dose)
- Qnexa 3.75/23 (low dose)

"The weight loss observed with Qnexa in these two one-year, double-blind, randomized trials far exceeds the weight loss observed for other agents reported in literature," said Kishore Gadde, MD, director of obesity clinical trials at Duke University

and a lead investigator. "The efficacy and safety results confirm the earlier findings of our phase 2 study, which showed a very good efficacy and benefit/risk profile. Importantly, the medical benefits of this treatment in reducing the risk of weight-related co-morbidities such as hypertension, diabetes, and dyslipidemia could establish Qnexa as a major advancement in the management of obesity."

EQUIP (OB-302) Results

The EQUIP study included 1,267 morbidly obese patients (1,050 females and 217 males) across 93 centers in the United States. The average baseline BMI of the study population was 42.1 kg/m² and baseline weight was 256 pounds. Patients had a 4-week dose titration period followed by 52 weeks of treatment. The study was a randomized, double-blind, placebo-controlled, 3-arm, prospective trial with patients randomized to receive once-a-day treatment with low-dose Qnexa, full-dose Qnexa or placebo. Patients were asked to follow a hypocaloric diet representing a 500-calorie/day deficit and advised to implement a simple lifestyle modification program. Results from the study are as follows:

EQUIP (OB-302) 56 Weeks	ITT-LOCF			Completers		
	Placebo (n=498)	Qnexa Low Dose (n=234)	Qnexa Full Dose (n=498)	Placebo (n=241)	Qnexa Low Dose (n=138)	Qnexa Full Dose (n=301)
Mean Weight Loss (%)	1.6%	5.1%*	11.0%*	2.5%	7.0%*	14.7%*
Greater than or equal to 5% weight loss rate	17%	45%*	67%*	26%	59%*	84%*

ITT-LOCF: Intent-to-treat with last observation carried forward

*p<0.0001 vs. placebo

- Average weight loss for Qnexa patients completing the EQUIP study was 37 pounds and 18 pounds with full-dose Qnexa and low-dose Qnexa, respectively, as compared to 6 pounds in the placebo group;
- 60% of the full-dose Qnexa patients who completed the study lost at least 10% of their baseline weight;
- 43% of the full-dose Qnexa patients who completed the study lost at least 15% of their baseline weight;
- Completion rate for EQUIP was 47%, 57%, 59% for patients taking placebo, low-dose Qnexa and full-dose Qnexa, respectively; and
- Patients treated with full-dose Qnexa had significant improvements in blood pressure, triglycerides and cholesterol.

CONQUER (OB-303) Results

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. Patients had a 4-week dose titration period followed by 52 weeks of treatment. 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, full-dose Qnexa or placebo. Patients were asked to follow a hypocaloric diet representing a 500-calorie/day deficit and advised to implement a simple lifestyle modification program. Results from the study are as follows:

ITT-LOCF	Completers
----------	------------

CONQUER (OB-303) 56 Weeks	Placebo (n=979)	Qnexa Mid Dose (n=488)	Qnexa Full Dose (n=981)	Placebo (n=564)	Qnexa Mid Dose (n=344)	Qnexa Full Dose (n=634)
Mean Weight Loss (%)	1.8%	8.4%*	10.4%*	2.4%*	10.5%*	13.2%*
Greater than or equal to 5% weight loss rate	21%	62%*	70%*	26%	75%*	85%*

*p<0.0001 vs. placebo

- Average weight loss for Qnexa patients who completed the CONQUER study was 30 pounds and 24 pounds with full-dose Qnexa and mid-dose Qnexa, respectively, as compared to 6 pounds in the placebo group.
- In the CONQUER study subset analysis, higher risk patients, defined as those in the upper 25th percentile of a specific co-morbidity, who were treated with full-dose Qnexa for 56 weeks achieved the following changes in cardiovascular risk factors:
 - Reduction in systolic blood pressure of 20 mmHg from 147 mmHg at baseline, as compared to a reduction of 14 mmHg in the placebo group (p<0.0001). This improvement occurred in the presence of a significant reduction in blood pressure medications in Qnexa-treated patients as compared to placebo;
 - Reduction in triglyceride levels of 98 mg/dL from 268 mg/dL at baseline, as compared to a decrease of 42 mg/dL from 262 mg/dL at baseline in the placebo group (p<0.0001);
 - Reduction in hemoglobin A1c levels of 0.6% from 7.3% at baseline as compared to a reduction of 0.1% from 7.4% at baseline for the placebo patients (p<0.0001). These improvements occurred in the presence of a significant reduction in antidiabetic medications in Qnexa-treated patients compared with placebo. All patients were treated to standard of care for type 2 diabetes. 64% of the full-dose Qnexa patients who completed the study lost at least 10% of their baseline weight;
 - 39% of the full-dose Qnexa patients who completed the study lost at least 15% of their baseline weight; and
- Completion rates for CONQUER were 57%, 69%, 64% for patients taking placebo, mid-dose Qnexa, and full-dose Qnexa, respectively.

Across both 56-week studies comprised of more than 3,750 patients, the most commonly reported side effects were dry mouth, tingling, constipation, altered taste and insomnia. Monthly assessments using prospective psychometric instruments in accordance with FDA's guidance showed no signal for suicidality risk. There were no suicide attempts or suicidal behaviors, and there was no signal for suicidal ideation across all treatment groups including placebo. Depression or depressed mood adverse events of a moderate to severe nature were less than 2% and were similar among patients in the Qnexa and placebo groups. Overall, depression scores, quality of life including self esteem and general health significantly improved for patients on Qnexa.

"I have seen dramatic and sustained weight loss with Qnexa as well as notable improvements in cardiovascular risk factors, diabetes, emotional well being and quality of life in my patients," commented Michelle Look, M.D., FAAFP, of the San Diego Sports Medicine and Family Health Center and a lead investigator in the studies. "What is so striking for me is how many of my patients were able to achieve weight loss with Qnexa for the first time after many years of battling weight problems without success. The excellent tolerability of Qnexa allowed patients to stay on therapy for a year, as evidenced by the strong completer rates."

Other Safety Studies

VIVUS completed a thorough QT prolongation (TQT) study evaluating subjects taking Qnexa. The study was completed with no

signal for QT prolongation. Subjects taking Qnexa also underwent complex and extensive cognitive and psychomotor testing using validated, FDA accepted testing methodologies. There was no clinically significant change in overall cognitive function or effect on psychomotor skills seen in patients taking Qnexa.

"These data are significant, and when coupled with my own experience treating patients with Qnexa, clearly demonstrate that it is one of the promising pharmaceutical therapies in development to assist patients in achieving significant weight loss," stated Louis Aronne, MD, Clinical Professor of Medicine and Director of the Comprehensive Weight Control Program at New York-Presbyterian Hospital/Weill Cornell Medical Center and one of the investigators involved in the clinical trials. "People with weight problems have a truly biologic disease, and we are in desperate need of more options and effective tools to help our patients combat this disease and the other serious medical conditions that arise as a result of weight gain. I am encouraged by the efficacy and safety seen in these late stage Qnexa trials."

Note to Investors

As previously announced, VIVUS will hold a conference call to discuss these results today, September 9, 2009, beginning at 8:00 a.m. Eastern Time. You can listen to this call by dialing toll free 1-800-967-7185, or 1-719-325-2352. A 30-day archive of the call can be accessed at <http://ir.vivus.com/>.

To access the webcast of this event, please visit: VIVUS' Investors site at <http://ir.vivus.com/events.cfm>. Replay will also be available on demand from the website at the conclusion of the program.

About Qnexa

Qnexa (Q-NEX-uh) is a once-a-day, proprietary, oral, controlled-release formulation of low dose phentermine and topiramate, which is believed to address both appetite and satiety - the two main mechanisms that impact eating behavior - in one capsule. Qnexa, an investigational drug, is being developed to address weight loss. In phase 2 and 3 clinical data to date, Qnexa has demonstrated significant weight loss, glycemic control, and improvement in cardiovascular risk factors.

About Obesity

More than 300 million people worldwide and approximately 30 percent of American adults (more than 60 million people) are obese, a chronic condition defined by having excess body fat. As the second leading cause of preventable death, obesity directly contributes to numerous life-threatening conditions including diabetes, cardiovascular disease, hypertension and stroke. Experts agree that even a modest weight loss of five percent of weight, maintained over time, can bring significant health benefits by lowering blood pressure and reducing the risk of diabetes and heart disease.

About VIVUS

VIVUS is a biopharmaceutical company developing innovative, next-generation therapies to address unmet needs in obesity, diabetes and sexual health. The company's lead product in clinical development, Qnexa(TM), has recently completed phase 3 clinical trials for the treatment of obesity. Qnexa is also in phase 2 clinical development for the treatment of type 2 diabetes. In the area of sexual health, VIVUS is in phase 3 development with avanafil, a potentially best-in-class PDE5 inhibitor, and in phase 2 development of Luramist(TM) for the treatment of hypoactive sexual desire disorder (HSDD) in women. 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, 2008 and periodic reports filed with the Securities and Exchange Commission.

CONTACT:

VIVUS, Inc.
Timothy E. Morris
Chief Financial Officer
650-934-5200

Investor Relations:
The Trout Group
Brian Korb
646-378-2923

Media Relations:
Pure Communications, Inc.
Sheryl Seapy
949-608-0841

Ashlea Kozikowski
910-509-3974

SOURCE VIVUS, Inc.

<http://www.vivus.com>

Copyright (C) 2009 PR Newswire. All rights reserved