



## **FDA Issues Complete Response Letter to VIVUS Regarding New Drug Application for QNEXA(R)**

### **VIVUS TO SUBMIT WRITTEN RESPONSE WITHIN SIX WEEKS**

MOUNTAIN VIEW, Calif., Oct 28, 2010 /PRNewswire via COMTEX News Network/ -- VIVUS, Inc. (Nasdaq: VVUS) announced today that it received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for the investigational new drug QNEXA(R) (phentermine/topiramate) Controlled-Release Capsules. The FDA issued the CRL to communicate its decision that the NDA cannot be approved in its present form. The application seeks the approval to market QNEXA as an oral, once-a-day formulation for the treatment of obesity, including weight loss and maintenance of weight loss, in patients who are obese or overweight with co-morbidities such as hypertension, type 2 diabetes, dyslipidemia or central adiposity.

The CRL included the following areas: clinical, labeling, REMS, safety update, and drug scheduling.

In the clinical section of the CRL, the FDA requested a comprehensive assessment of topiramate's and phentermine/topiramate's teratogenic potential. This will include a detailed plan and strategy to evaluate and mitigate the potential teratogenic risks in women of childbearing potential taking the drug for the treatment of obesity. In addition, the FDA asked VIVUS to provide evidence that the elevation in heart rate associated with phentermine/topiramate does not increase the risk for major adverse cardiovascular events.

The FDA requested that VIVUS formally submit the results from the already completed SEQUEL study (OB-305), a 52-week extension study for a subset of 675 patients who completed the previously reported 56-week CONQUER study. Top-line results from the two-year SEQUEL study were announced by VIVUS on September 21, 2010 and a final study report is being prepared for submission to the NDA.

The FDA reserved the right to comment further on proposed labeling. On REMS, the FDA requested that a discussion of an already submitted REMS plan be continued after the written response from VIVUS has been submitted. The agency also requested a safety update of any new adverse events be submitted to the NDA. Finally, the FDA stated that if approved, phentermine/topiramate would be a Schedule IV drug due to the phentermine component.

As part of the written response, VIVUS plans to compile analyses integrating existing nonclinical and clinical data to provide a comprehensive assessment of the teratogenic potential of topiramate. In addition, VIVUS plans to provide several new analyses to demonstrate QNEXA does not increase the risk for major cardiovascular events, which would include data from our OB-305 and OB-204 studies. In the CRL, no new clinical studies were requested; however, in the event that any of the FDA concerns are not alleviated, additional clinical studies may be required.

"We remain confident in the efficacy and safety profile of QNEXA demonstrated in the clinical development program and look forward to continue working with the FDA towards the approval for the treatment of obesity," said Leland Wilson, chief executive officer of VIVUS. "We are preparing a comprehensive response to the CRL for submission to the FDA in approximately six weeks."

### **Note to Investors**

VIVUS will hold a conference call to discuss this update on Friday, October 29, 2010, beginning at 8:30 a.m. Eastern Time. Investors can listen to this call by dialing toll-free 877-359-2916 or 224-357-2386. 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>. A replay will also be available on demand from the website at the conclusion of the program.

### **About Obesity**

Approximately one-third of American adults (more than 72 million people) are obese, and many more are overweight with co-morbidities. Obesity is a chronic condition defined by having excess body fat. Obesity significantly increases the risk of

developing many different diseases and health conditions, including type 2 diabetes, hypertension, metabolic syndrome, cardiovascular disease, some cancers and osteoarthritis. According to a report in *The Lancet* in 2009, morbid obesity shortens life expectancy by approximately 10 years, and moderate obesity shortens it by approximately 3 years.

Beyond its impact on health, obesity accounts for 9.1% of US annual health care spending - nearly \$150 billion. By 2030, if trends in the escalating rates of obesity continue, healthcare costs attributable to obesity may reach \$956 billion, accounting for up to 18% of total health care costs or \$1 of every \$6 spent on health care.

In August of this year, the CDC called attention to the "major public health problem" of obesity by issuing a national report citing the lack of progress against goals established 10 years ago by the federal government. The agency reported that all 50 states failed to meet the "Healthy People 2010" goal of lowering the obesity rate to 15%, and some states actually reported a significant increase in obesity rates. The agency includes obesity among six areas of focus in its "Winnable Battles" campaign to identify strategies, resources and partnerships to accelerate a measurable impact on health.

### **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 is QNEXA(R), which also is 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](http://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, the timing and substance of VIVUS' response to the FDA's complete response letter; the FDA's interpretation of the data VIVUS submits relating to the teratogenicity and cardiovascular safety; the FDA's interpretation of the data from our SEQUEL study (OB-305); that we may be required to conduct additional clinical trials; substantial competition; uncertainties of patent protection and litigation; 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 our response to the FDA's complete response letter will be sufficient to satisfy the FDA's safety concerns, that the FDA will not require us to conduct additional clinical studies 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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