VIVUS Announces Date of FDA Advisory Committee Review of Qnexa for the Treatment of Obesity

Bio-Medicine.Org

MOUNTAIN VIEW, Calif., Dec. 23, 2011 /PRNewswire/ -- VIVUS, Inc. (NASDAQ: VVUS [1]) today announced that the Endocrinologic and Metabolic Drugs Advisory Committee of the U.S. Food and Drug Administration (FDA) is scheduled to review the Company's New Drug Application (NDA) for Qnexa for the treatment of obesity on February 22, 2012. VIVUS resubmitted the NDA on October 17, 2011 seeking approval to market Qnexa in the United States. The FDA accepted the NDA for review on November 3, 2011. The target date for the FDA to complete its review of the Qnexa NDA is April 17, 2012.

About QnexaQnexa [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 investigational 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. VIVUS received a Complete Response Letter, or CRL, to the initial Qnexa NDA on October 28, 2010. We resubmitted the Qnexa NDA in October 2011, with an FDA action date of April 17, 2012. Qnexa is also in phase 2 clinical development for the treatment of type
'/>"/>

SOURCE [2]

Source URL (retrieved on *12/10/2013 - 2:51am*):
http://www.mdtmag.com/news/2011/12/vivus-announces-date-fda-advisory-committee-review-qnexa-treatment-obesity

Links:

[1] http://studio-5.financialcontent.com/prnews?Page=Quote&Ticker=VVUS
[2] http://www.bio-medicine.org/medicine-technology-1/VIVUS-Announces-Date-of-FDA-Advisory-Committee-Review-of-Qnexa-for-the-Treatment-of-Obesity-23117-1/