



November 2, 2017

## **VIVUS Completes Tacrolimus Pre-IND Meeting With FDA**

### **Company on track to initiate clinical trials in 2018**

CAMPBELL, CA -- (Marketwired) -- 11/02/17 -- VIVUS, Inc. (NASDAQ: VVUS) (the "Company"), a biopharmaceutical company committed to the development and commercialization of innovative therapies focusing on treatments for patients with serious unmet medical needs, today announced that it held a pre-IND meeting with the U.S. Food and Drug Administration (FDA) in October for its proprietary formulation of tacrolimus for the treatment of pulmonary arterial hypertension (PAH). The FDA addressed VIVUS' questions related to preclinical, nonclinical and clinical data and planned design of clinical trials of tacrolimus in class III and IV PAH patients, and clarified the requirements needed to file an IND to initiate a clinical trial in this indication. VIVUS is on track to file this IND in the first half of 2018. As discussed with the FDA, VIVUS currently intends to design and conduct clinical trials that could qualify for Fast Track and/or Breakthrough Therapy designation.

"Our meeting with the FDA was an important step forward and the guidance we received during our pre-IND meeting was valuable in our development of clinical and regulatory strategies that will support our goal of advancing tacrolimus into and through clinical development," said Seth H. Z. Fischer, VIVUS' Chief Executive Officer. "We believe that our tacrolimus development program holds great potential as an innovative therapy that can help to address the unmet clinical needs of patients living with PAH, including preventing disease progression and/or disease modification."

PAH is a degenerative disease that makes it difficult for the heart to pump blood to the lungs to be oxygenated and may ultimately lead to heart failure. Current PAH treatment options only address the symptoms, slowing but not preventing disease progression. New therapies that address the underlying cause of disease are urgently needed. VIVUS is developing a proprietary formulation of tacrolimus for the treatment of PAH.

The FDA approved tacrolimus in 1994 for use in lowering the risk of organ rejection in patients undergoing kidney transplant, and is currently indicated for use in additional organ transplant settings and to treat atopic dermatitis. Tacrolimus has been shown to increase signaling through the bone morphogenetic protein receptor 2 (BMP2) pathway, which is down-regulated in PAH patients.

#### **About VIVUS**

VIVUS is a biopharmaceutical company committed to the development and commercialization of innovative therapies that focus on advancing treatments for patients with serious unmet medical needs. 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 and are subject to risks, uncertainties and other factors, including risks and uncertainties related to potential change in our business strategy to enhance long-term stockholder value; risks and uncertainties related to our ability to successfully develop or acquire a proprietary formulation of tacrolimus as a precursor to the clinical development process; risks and uncertainties related to our ability to continue to identify, acquire and develop innovative investigational drug candidates and drugs; risks and uncertainties related to the failure to obtain FDA or foreign authority clearances or approvals and noncompliance with FDA or foreign authority regulations; risks and uncertainties related to our ability to develop a proprietary formulation and to demonstrate through clinical testing the quality, safety, and efficacy of our current or future investigational drug candidates; and risks and uncertainties related to the timing of initiation and completion of clinical trials and submissions to U.S. and foreign authorities. These risks and uncertainties could cause actual results to differ materially from those referred to in these forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. Investors should read the risk factors set forth in VIVUS' Form 10-K for the year ended December 31, 2016 as filed on March 8, 2017 and as amended by the Form 10-K/A filed on April 26, 2017, and periodic reports filed with the Securities and Exchange Commission. VIVUS does not undertake an obligation to update or revise any forward-looking statements.

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