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Ventrus Announces Publication of Prior Phase 2b Study on the Safety and Efficacy of Iferanserin in the Treatment of Hemorrhoid Disease

NEW YORK, Jan. 13, 2012 (GLOBE NEWSWIRE) -- Ventrus BioSciences, Inc. (Nasdaq:VTUS), today announced the online publication of the prior Phase 2b study utilizing iferanserin (VEN 309), its novel investigational drug for the treatment of symptomatic hemorrhoids, in the peer reviewed journal *Clinical Therapeutics*. The article will appear in the February issue of Clinical Therapeutics and is currently available online at the following link http://www.sciencedirect.com/science/journal/aip/01492918. Data from this trial have been previously disclosed by the company.

The double-blind, placebo-controlled study, conducted between September 2001 and August 2002, randomized 121 patients at five colorectal surgery sites in Germany. The principal investigator and lead author of the paper is Prof. Dr. Alexander Herold of Mannheim, Germany. Compared with placebo, iferanserin significantly reduced patient-reported severity of daily bleeding beginning at day 1 and itching beginning at day 2 ($P < 0.05$). The effects were sustained throughout the 14-day treatment period. There was also a reduction in patient-reported severity of daily pain seen with iferanserin treatment. Adverse events were mild and infrequent and did not differ significantly between treatment groups.

The paper also presents the results from a *post hoc* analysis of the data using endpoints that Ventrus has adopted for its ongoing Phase 3 pivotal trial being conducted in 600 patients at 70 centers in the US. The primary endpoint in this ongoing Phase 3 study is cessation of bleeding by day 7 through day 14 (second week of treatment). In the German Phase 2b study, it was determined that 57% of iferanserin-treated patients had cessation of bleeding versus only 20% of placebo-controlled patients ($P = 0.0001$). The secondary endpoints of the ongoing Phase 3 study are cessation of itching and pain by day 7 through day 14. In the German Phase 2b study, the data showed that 59% of iferanserin-treated patients versus 32% of placebo-controlled patients ($P = 0.034$) had cessation of itching, while pain ceased at day 7 and did not return by day 14 in 50% of iferanserin-treated patients versus 18% of placebo-treated patients ($P = 0.032$).

"The findings of this Phase 2b German trial were significant in defining the targeted patient population and developing meaningful endpoints for our ongoing pivotal Phase 3 trial for iferanserin. The therapeutic benefits observed in the Phase 2b trial suggest a potential role for iferanserin for the treatment of symptomatic hemorrhoids," said Dr. Russell Ellison, Chairman and Chief Executive Officer of Ventrus BioSciences, Inc.

Dr. Ellison elaborated, "As recently observed through our omnibus market research, consumers who have suffered from hemorrhoids in the past year constitute approximately 10% of the US adult population, with the vast majority seeking a medical solution."

Ventrus anticipates reporting the top line data from its ongoing US Phase 3 trial of iferanserin in hemorrhoids in June of 2012, and the data from the European Phase 3 trial of VEN 307 (diltiazem cream) for the treatment of anal fissures in May 2012 (this study completed enrollment in December 2011).

About Ventrus

Ventrus is a development stage specialty pharmaceutical company focused on the development of late-stage prescription drugs for gastrointestinal disorders. Our lead products are: Iferanserin (VEN 309) for the topical treatment of hemorrhoids, for which the first Phase 3 clinical trial began in August 2011 and is ongoing, and topical diltiazem (VEN 307) for the treatment of anal fissures for which the first Phase 3 trial was initiated in November 2010, and is ongoing. Our product candidate portfolio also includes topical phenylephrine (VEN 308) intended to treat fecal incontinence. VEN 307 and VEN 308 are two molecules that were previously approved and marketed for other indications and that have been formulated into our in-licensed proprietary topical treatments for these new gastrointestinal indications. VEN 309 is a New Chemical Entity (NCE).

Please Note: The information provided herein contains estimates and other forward-looking statements regarding future events. Such statements are just predictions and are subject to risks and uncertainties that could cause the actual events or results to differ materially. These risks and uncertainties include, among others: the timing, cost and results of clinical trials and other development activities involving our product candidates; the unpredictability of the clinical development of our product candidates and of the duration and results of regulatory review of those candidates by the FDA and foreign regulatory authorities; the unpredictability of the size of the markets for, and market acceptance of, any of our products, including VEN 309; our anticipated capital expenditures, our estimates regarding our capital requirements, and our need for future capital; our

ability to retain and hire necessary employees and to staff our operations appropriately; and the possible impairment of, or inability to obtain, intellectual property rights and the costs of obtaining such rights from third parties. The reader is referred to the documents that we file from time to time with the Securities and Exchange Commission.

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