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Ventrus Validates Large Patient Potential for VEN 309 With Survey Data From 10,000 Consumers

Expects to Deliver Top Line Results From Two Pivotal Trials in Mid-2012 and to Complete the Acquisition of the Global Rights and Title for VEN 309 From the Licensor

NEW YORK, Nov. 14, 2011 (GLOBE NEWSWIRE) -- Ventrus BioSciences, Inc. (Nasdaq:VTUS) announced today an update to the timing for the reporting of the top line results from the ongoing Phase 3 pivotal trial of Iferanserin (VEN 309) in patients with hemorrhoids as well as from the ongoing Phase 3 pivotal trial of Diltiazem (VEN 307) in patients with anal fissures. The company has extended the timing to report the top line results from the hemorrhoid trial by approximately three months, to around June 2012 while top line data for the anal fissure trial is still expected around May 2012.

"Both trials are progressing well with respect to data quality and GCRP (Good Clinical Research Practices). As we expect to report top line Phase 3 results for both products in the second quarter of 2012, these milestones are likely to be close together in time," said Dr. Russell Ellison, Chairman and Chief Executive Officer of Ventrus. "Our projected NDA filing timelines for both VEN 309 and VEN 307 remain on track, and the new completion timelines for VEN 309 should have no material effect on the balance sheet."

Additionally, the company commissioned Princeton Brand Econometrics (PBE) to conduct a landmark omnibus survey of consumers and patients. From these data, PBE is developing a predictive model to forecast physician and patient behavior in response to various product profiles and promotional levels.

Initial results from the market research show that the hemorrhoid market is potentially large, patients are seeking solutions, and respond strongly to the VEN 309 product concept. Of the 10,202 adult consumers surveyed, 1,125 patients reported having hemorrhoids within the last two years, which represents approximately 11% of the US adult population (25.8 million of 234 million people). In addition to the 11% two year prevalence, 9%, 6% and 3% reported having hemorrhoids within the past one year (21.7 million people), one month (14 million people) and on the day of survey (6.7 million people) respectively. Of the entire group of hemorrhoid patients surveyed, 85% reported having had treatment at some point; from the treatment subset, 86% reported using OTC and 14% using prescription products as their last treatment. 10% of all hemorrhoid patients surveyed had had an invasive procedure (banding, injection, surgery) at some time, of which 61% had surgery, and 75% of patients who had had an invasive procedure reported a recurrence.

Patients had a strong response to the product concept of VEN 309 as a treatment for their hemorrhoids. Of the 1,125 hemorrhoid patients surveyed, 75% stated that they would request a prescription at their next physician visit. At industry standard promotional levels, the PBE factored modeling calculates that 25% of this large population would actually request the prescription. For those patients experiencing hemorrhoids on the day of the survey, 88% stated they would request a prescription and the PBE factoring model calculates that 80% would actually make the request. In addition, for the entire sample, including all income levels, of those actually receiving a prescription, 66% would fill it with a $35 out-of-pocket patient co-pay.

The company expects to close the acquisition of the global rights and title for VEN 309 from the licensor, Sam Amer & Co., today as the major conditions required for the close have been met. "Given what we have discovered about the commercial potential of VEN 309, the progress of the development program, and what we have learned about the details of the regulatory pathway and the potential market and data exclusivity, we are very pleased to be able to finalize this transaction," said Dr. Ellison. "We believe that this could considerably enhance the value of this asset to the company."

The Company will conduct a conference call and webcast today, November 14, at 8:00 A.M. EST, to discuss the financial results, clinical program updates, and the third party market research survey. The call and webcast are open to any interested party. To listen to the conference call, dial in approximately ten minutes before the scheduled call to (877) 293-5456 (U.S.); (707) 287-9357 (international), passcode 26472909. A live, audio-only webcast is also available on the Company's website at http://investor.ventrusbio.com/events.cfm. The audio webcast of the conference call will be accessible following the live broadcast through December 5, 2011. Additional information is also available on the company's website at ventrusbio.com

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 III clinical trial began in August 2011 and is ongoing, and topical Diltiazem for the treatment of anal fissures for which the first Phase III trial was initiated November 2010, and is ongoing. Our product candidate portfolio also includes topical phenylephrine intended to treat fecal incontinence (VEN 308). 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, and VEN 309 is a New Chemical Entity (NCE)

About Princeton Brand Econometrics

Princeton Brand Econometrics (PBE) is a marketing engineering consultancy headquartered in Princeton, NJ, that builds models which simulate the cause and effect dynamics of market environments of interest, based on extensive and rigorous quantitative research. PBE's average forecast error across 31 published validations is ± 2.68% of actual in-market outcomes, and its forecasting methodology has been utilized by 9 of the 10 top pharmaceutical companies.

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; the risks of not closing the acquisition of VEN 309 from Sam Amer & Co.; 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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