May 9, 2012

Ventrus Biosciences Reports First Quarter 2012 Financial Results

NEW YORK, May 9, 2012 (GLOBE NEWSWIRE) -- Ventrus Biosciences, Inc. (Nasdaq:VTUS) today reported financial results for the first quarter ended March 31, 2012.

"Ventrus has achieved several important milestones in recent months, namely the completion of enrollment in pivotal Phase 3 clinical trials for our two lead product candidates, diltiazem for anal fissures and iferanserin for hemorrhoids," said Russell H. Ellison, M.D., M.Sc., Chairman and Chief Executive Officer of Ventrus Biosciences, Inc. "These milestones put us on track to report top-line results from the diltiazem study this month and the iferanserin study in late June, early July. With late stage results expected in the immediate and near future and a strong balance sheet, Ventrus remains well positioned to bring new, innovative treatments to areas of unmet need in gastroenterology."

First Quarter 2012 Financial Results

Ventrus ended the first quarter of 2012 with $31.1 million in cash and cash equivalents and no debt.

Ventrus reported a net loss of approximately $8.2 million ($.66 per share) for the three months ended March 31, 2012 compared to a net loss of approximately $2.7 million for the three months ended March 31, 2011. Net cash used in operating activities was approximately $6.1 million for the three months ended March 31, 2012 compared to approximately $1.8 million for the three months ended March 31, 2011. The primary reason for the difference between the net loss and the net cash used in operating activities for the three months ended March 31, 2012 is stock-based compensation charges of approximately $1.0 million and an increase in accounts payable of approximately $1.2 million.

Research and development expenses for the three months ended March 31, 2012 increased to approximately $6.4 million from approximately $970,000 in the same period last year as we moved our product development programs forward. General and administrative expenses for the three months ended March 31, 2012 increased to $1.8 million from $1.7 million in the same period last year.

We believe that our existing cash and cash equivalents at March 31, 2012, will be sufficient to enable us to fund our projected operating expenses and capital expenditure requirements into the third quarter of 2013.

First Quarter 2012 and Recent Highlights

- **Announced Completion of Enrollment in Pivotal Phase 3 Trial of Diltiazem (VEN 307) in Patients with Anal Fissures.** In December 2011, Ventrus announced completion of patient enrollment and randomization in its Phase 3, randomized, double-blind, placebo-controlled clinical trial of Diltiazem (VEN 307) in patients with anal fissures. Consistent with the protocol for this trial, 465 patients have been randomized to diltiazem hydrochloride 2% or 4% cream, or placebo for 8 weeks of treatment, to be followed by a 4 week blinded observation period. Initial top-line data from the study is expected to be available in May 2012.

- **Announced Completion of Enrollment in Pivotal Phase 3 Trial of Iferanserin (VEN 309) in Patients with Hemorrhoidal Disease.** In April, Ventrus announced completion of patient enrollment and randomization in its Phase 3, randomized, double-blind, placebo-controlled clinical trial of iferanserin (VEN 309) in patients with grade 1-3 hemorrhoids. Consistent with the protocol for this trial, 604 patients have been randomized to one of three twice daily treatment groups: 7 days of active treatment followed by 7 days of placebo, 14 days of active treatment, or 14 days of placebo treatment. Data from the study are anticipated to be available in late June or early July 2012.

- **Announced Presentation of Data from Two Hemorrhoid Studies at Digestive Disease Week 2012.** Ventrus will be presenting data from two studies addressing hemorrhoidal disease at Digestive Disease Week 2012 taking place May 19-22, 2012 in San Diego, CA. Both abstracts present data from the omnibus patient survey commissioned by Ventrus of 10,202 consumers and 1,125 hemorrhoidal disease (HD) patients, which studied the epidemiology, natural history and treatment of HD in the US. The first abstract, "History of Treatment of Hemorrhoid Disease," was selected for an oral platform presentation. The second abstract, "Epidemiology and Natural History of Hemorrhoid Disease," was selected for poster presentation.

- **Announced Publication of Iferanserin Phase 2b Data in *Clinical Therapeutics*.** In January, the Company

announced the publication of a 2001/2002 Phase 2b, double-blind, placebo-controlled study of iferanserin (VEN 309) for HD in the February 2012 issue of the peer reviewed journal *Clinical Therapeutics.* The study, which randomized 121 patients at five colorectal surgery sites in Germany, demonstrated that, 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 of iferanserin.

About Ventrus

Ventrus is a development stage 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 hemorrhoidal disease, for which the first Phase 3 clinical trial began in August 2011 and has completed enrollment, and topical diltiazem (VEN 307) for the treatment of anal fissures for which the first Phase 3 trial was initiated in November 2010, and has completed the dosing of patients. 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.

CONTACT: Ventrus Biosciences, Inc.

David Barrett

646-706-5208

dbarrett@ventrusbio.com

Argot Partners

David Pitts

212-600-1902

david@argotpartners.com

Source: Ventrus BioSciences