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Ventrus Biosciences Completes Enrollment of Pivotal Phase 3 Trial of Iferanserin (VEN 309) in Patients With Hemorrhoidal Disease

Results Are Anticipated in Late June to Early July - 2012

NEW YORK, April 30, 2012 (GLOBE NEWSWIRE) -- Ventrus Biosciences, Inc. (Nasdaq:VTUS) announced that it has completed patient enrollment and randomization in the first Phase 3 clinical trial of iferanserin (VEN 309) in patients with grade 1-3 hemorrhoids. Data from the Phase 3 study are anticipated to be available in late June or early July 2012.

The Phase 3 study is a randomized, double-blind, placebo-controlled trial to evaluate the safety and efficacy of iferanserin ointment in subjects with grade 1-3 hemorrhoids and is being conducted in more than 70 centers in the US. Elimination of bleeding from day 7 through day 14 of treatment is the primary endpoint, with elimination of itching and pain from day 7 through day 14 as the secondary endpoints. All patients were required to show meaningful symptoms (bleeding, plus either itching or pain for 2 consecutive days immediately prior to randomization) to be enrolled. 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. Enrollment into this large trial began in August 2011, and was completed in only 8 months.

"This is an important milestone in the clinical development of VEN 309, and marks completion of enrollment in the largest-known randomized, placebo-controlled clinical trial for the treatment of hemorrhoidal disease," said Dr. Russell Ellison, Chairman and Chief Executive Officer of Ventrus Biosciences, Inc. "Ventrus is focused on bringing the treatment of hemorrhoidal disease into the modern medical era by developing the first prescription pharmaceutical treatment for FDA approval, for the relief of symptoms — an advancement which could benefit millions of patients who suffer from hemorrhoids."

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

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