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Ventrus Announces the Launch of the First Pivotal Trial of VEN 309 for the Treatment of Hemorrhoids

NEW YORK, Aug. 16, 2011 (GLOBE NEWSWIRE) -- Ventrus BioSciences, Inc. (Nasdaq:VTUS) announced today that enrollment has opened at 65 of the 70 sites that will participate in the first pivotal Phase III trial of VEN 309 for the treatment of symptomatic hemorrhoids, and patients have now entered the screening process. Ventrus expects that the dosing of the first patients will begin the week of August 22 2011, and that the remaining 5 sites will be initiated in the current quarter. "We are excited to begin the pivotal Phase III trial for VEN 309 for the treatment of hemorrhoids, as planned," said Russell H. Ellison MD, Chairman and CEO of Ventrus, "particularly as this is the first Phase III trial in the U.S. for a drug treatment for patients with this condition, for whom there are currently no FDA-approved prescription drugs available."

About Iferanserin (VEN 309)

Iferanserin (VEN 309) is a new chemical entity, or NCE, in late stage development, for the topical treatment of hemorrhoids, which targets a specific serotonin receptor (5HT2A) thought to be important in the disease and is applied topically, twice per day.

About the Phase III Trial

The Phase III trial of VEN 309 has been designed to include approximately 600 patients in a double-blind, 3-arm design. Iferanserin (0.5%) ointment, applied intra-anally twice per day, using a single-use tube and applicator, will be compared with matching placebo ointment in the following cohorts:

1. Iferanserin for 14 days,
2. Iferanserin for 7 days followed by placebo for 7 days, and
3. placebo for 14 days.

All patients will be evaluated in the double blind period for follow-up at 28 days, and subsequently all patients will enter a 12 month open label extension part of the study where they will have access to treatment with active drug if they have a recurrence of symptoms, to assess longer term safety and recurrence rates. The primary endpoint of this trial will be cessation of bleeding on days 7 to 14 and the secondary endpoints are cessation of pain and itching days 7 to 14. Data from the double-blind part of the study, and recurrence rates up to that point, are expected in the first quarter of 2012.

More details about the trial VEN309-Hem-SE3-001 may be found at www.clintrials.gov (search NCT01355874**)**

About Ventrus

Ventrus is a development stage specialty pharmaceutical company focused on the development of late-stage prescription drugs for gastrointestinal disorders. Our lead product is iferanserin (VEN 309) for the topical treatment of hemorrhoids. Our additional product candidate portfolio consists of two in-licensed late-stage drugs intended to treat anal fissures (VEN 307) and fecal incontinence (VEN 308). The first Phase III clinical trial with VEN 307 has begun in Europe and we expect data to be available in the second quarter of 2012. These candidates are two molecules that were previously approved and marketed for other indications and that have been formulated into our proprietary topical treatments for these new gastrointestinal indications.

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; our anticipated capital expenditures and our estimates regarding our capital requirements; 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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