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Ventrus Adds Third Treatment Arm of Shorter Treatment Duration to Its Phase III Study of Iferanserin in Hemorrhoids

NEW YORK, May 2, 2011 (GLOBE NEWSWIRE) -- Ventrus BioSciences, Inc. (Nasdaq:VTUS) announced today that it has added a third treatment arm to its first pivotal Phase III study of Iferanserin (VEN 309), the first prescription product candidate for the treatment of hemorrhoids. The treatment arm has been added based upon a request from the U.S. Food and Drug Administration (FDA) in their response to the company's March 16, 2011 submission of the protocol for the study, made under a Special Protocol Assessment (SPA), and upon a new analysis of a prior Phase IIB study.

In its response, the FDA proposed that the company include an additional one week treatment arm in the pivotal study to evaluate whether patients could be fully treated within 7 days.

"When we analyzed our Phase IIB German study that compared Iferanserin given twice daily for 14 days, with placebo, using these endpoints, we observed that the majority of Iferanserin treated patients started their response by Day 3. This raises the possibility that Iferanserin therapy may require a shorter duration of treatment to show adequate efficacy to stop the bleeding, itching and pain associated with hemorrhoids," said Russell H. Ellison MD, CEO of Ventrus Biosciences. "It's not only good development practice to explore the possibility of a shorter treatment period as proposed by FDA's feedback, but should this regimen prove to be effective, it could be even more acceptable to patients," Dr. Ellison noted.

Following the feedback from the FDA, the double-blinded randomized trial design of the three arms would consist of:

Arm 1: placebo ointment twice daily intra-anally for 2 weeks;

Arm 2: Iferanserin ointment twice daily for 2 weeks; and

Arm 3: Iferanserin ointment twice daily for 1 week followed by placebo ointment twice daily for 1 week.

In its response to the SPA submission the FDA agreed with the definition of the primary and secondary endpoints that had been proposed and with the basic design elements of the study. The primary endpoint for all three arms will therefore be the proportion of patients who have no bleeding from the beginning of the 7^{th} day of treatment to the end of the 14^{th} and last day of treatment as previously announced. The secondary endpoints of pain and itching are similarly defined.

"We will go forward with the FDA proposal and submit a revised protocol under the SPA with the additional treatment arm in a timely fashion. We do not expect that this modification will materially change the timing to report the top line data, which we still expect will occur in the first quarter of 2012, in accordance with previous guidance," said Dr. Ellison.

About Iferanserin (VEN 309)

Iferanserin (VEN 309) is a new chemical entity, or NCE, for the topical treatment of hemorrhoids, which targets a specific serotonin receptor (5HT2A) thought to be important in the disease. The first late phase clinical trial (Phase III) with Iferanserin is expected to start in the summer of 2011 and we expect data to be available in the first quarter of 2012.

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 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 cost, timing and results of clinical trials and other development activities involving our product candidates; 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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