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Ventrus Announces Improved, FDA-Recommended Endpoints Proposed for Phase III Hemorrhoid Study

Company to Host Conference Call on Monday, March 21 at 8:30 AM ET

NEW YORK, March 18, 2011 (GLOBE NEWSWIRE) -- Ventrus BioSciences, Inc. (Nasdaq:VTUS) has filed a revised protocol with the U.S. Food and Drug Administration (FDA) under a Special Protocol Assessment (SPA) with new, more robust definitions for efficacy endpoints that were recommended by the FDA in a recent meeting with the company for the first pivotal study of the company's iferanserin (VEN 309) ointment, the first prescription product candidate for the treatment of hemorrhoids. Ventrus also announced that it will host a conference call on Monday, March 21 at 8:30 AM ET to discuss the proposed revised endpoints.

Russell H. Ellison, MD, Ventrus' CEO said the company is "very pleased with the new endpoint definitions in that they showed considerable differences between active drug and placebo in our analysis of an earlier Phase IIb study in Germany, which has been the cornerstone of our development program."

"In addition, we believe that the new endpoint definitions have the potential to provide a much stronger label which could further serve to encourage faster and broader adoption by physicians and by their patients who suffer the pain and discomfort of hemorrhoids," said Dr. Ellison. There is currently no FDA-approved prescription product for the treatment for hemorrhoids.

Ventrus submitted a new SPA on March 16, 2011, that includes a revised protocol, including the newly defined endpoints, in accordance with the feedback received from that meeting, and expects a response within 45 days, which is the customary FDA review period. The SPA remains subject to FDA agreement.

The pivotal Phase III clinical study for the treatment of hemorrhoids is expected to start on schedule, in mid-summer of this year.

For more detailed information on the endpoints please refer to our current report on Form 8-K filed today with the Securities and Exchange Commission and our website at ventrusbio.com

Conference Call Monday, March 21 at 8:30 AM ET

Ventrus will discuss the proposed revised endpoints in a conference call on Monday, March 21, 2011, at 8:30 AM Eastern Time. Interested investors may participate in the conference call by dialing 1-888-853-9372 (domestic) or 1-720-496-1609 (international), and entering passcode 634075 when prompted. The archived webcast of the conference call will be available for two weeks on Ventrus' web site at www.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 product, 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 mid-year 2011 and we expect data to be available in the first quarter of 2012. 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.

CONTACT: Ventrus Biosciences, Inc.

David Barrett

212-554-4506

dbarrett@ventrusbio.com

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