



November 5, 2012

Ventrus Biosciences Receives FDA Written Feedback, Targets NDA Filing for Diltiazem (VEN 307) in Anal Fissures Following Second Phase 3 Study

NDA Filing Expected to Occur in Fourth Quarter 2013

Company to Host Conference Call and Presentation Today, November 5, at 10:00 a.m. ET

NEW YORK, Nov. 5, 2012 (GLOBE NEWSWIRE) -- Ventrus Biosciences, Inc. (Nasdaq:VTUS) a pharmaceutical company focused on developing and commercializing gastrointestinal products, today announced that, following the receipt of written feedback from the U.S. Food and Drug Administration (FDA), the Company expects to file a new drug application (NDA) for diltiazem hydrochloride cream (VEN 307) in anal fissures following completion of a second Phase 3 study. Ventrus has started to enroll in its second Phase 3 pivotal trial, with results expected early fourth quarter 2013, and assuming a successful outcome, expects to file an NDA late in the fourth quarter of 2013 with an anticipated PDUFA date at the end of 2014. Ventrus also received specific guidance on the remaining toxicology programs, clinical cutaneous safety studies, and PK study required for the NDA and all programs are underway.

The second pivotal Phase 3 trial, a Phase 3b, Randomized, Double-Blind, Placebo-Controlled, Parallel-Treatment Group, Multicenter Efficacy and Safety Study of Topical Diltiazem Hydrochloride 2% Cream in Subjects with Anal Fissure, is planned to enroll 400 subjects at approximately 120 clinical sites in the U.S., Canada, and Israel. The primary objective is to evaluate the efficacy of diltiazem hydrochloride cream on reduction of worst anal fissure-related pain associated with or following defecation when administered three times a day for 28 days. The secondary objectives are to evaluate the effect of diltiazem hydrochloride cream on reduction of overall daily AF-related pain and to evaluate patient global impression of improvement (PGI-I) at Day 29 in subjects with AF-related pain.

"As we anticipated, the FDA has guided that an additional study of VEN 307 in patients with anal fissures will be required to be part of our planned NDA," said Russell H. Ellison, M.D., M.Sc., Chairman and Chief Executive Officer of Ventrus Biosciences, Inc. "We expect that the second study will allow us to confirm the positive results from the first pivotal Phase 3 study, and may enable us to expand our product label to include reduction in average daily pain in addition to pain on defecation. We look forward to bringing VEN 307, as expeditiously as possible, to those suffering from anal fissures."

In May 2012, Ventrus reported that its first pivotal Phase 3, randomized, double-blind, placebo-controlled clinical trial of VEN 307 for the treatment of anal fissures met its endpoints. The trial randomized 465 subjects to diltiazem hydrochloride 4% or 2% w/w cream, or placebo, applied topically three times daily (TID) for 8 weeks, followed by a 4 week blinded observation period.

At 4 weeks, the 2% diltiazem treatment arms demonstrated improvements compared to placebo in the primary endpoint of average of worst anal pain associated with or following defecation (pain score improvement of 0.43, $p=0.0122$) and in the secondary endpoints of overall anal-fissure-related pain (pain score of 0.42, $p=0.0143$). Pain endpoints were assessed using an 11-point numerical pain rating scale (Likert-like scale).

Because diltiazem is approved in oral formulations for the treatment of angina and high blood pressure, VEN 307 is eligible for the FDA's 505(b)2 registration pathway.

Conference Call and Presentation

The Company is hosting a conference call today, November 5, at 10:00 a.m. Eastern Time. To participate on the call, interested parties may dial 1-888-330-6585 (Toll-Free/North America) or 1-253-237-1143 (International/Toll) and use Conference ID: 64537164 to register ten minutes before the call is scheduled to begin. The call and an accompanying presentation will be broadcast live on the internet at <http://www.ventrusbio.com>.

The call will be archived for replay on November 5 at 1:00 p.m. Eastern Time and will remain available until November 12. The replay can be accessed at 1-855-859-2056 (Toll-Free/North America) or 1-404-537-3406 (International/Toll) using Conference ID: 64537164. An audio replay of the call will also be available on the Company's website, <http://www.ventrusbio.com>, for 30 days after 1:00 p.m. Eastern Time, November 5.

About VEN 307: Diltiazem Hydrochloride Cream

Diltiazem hydrochloride is a calcium-channel blocker that has been marketed in oral formulations for the treatment of angina

and high blood pressure for over two decades. Diltiazem hydrochloride cream is applied perianally to treat pain related to anal fissure. It has been shown to normalize internal anal sphincter pressure and reduce anal maximal resting pressure, or MRP, and its vasodilator activity has the potential to improve blood supply, thereby decreasing the pain associated with anal fissures.

About Anal Fissures

Anal fissure is a tear in the lining of the anal canal. It is a common anal disorder characterized by severe anal pain, associated with or after bowel movements. The pathogenesis of anal fissure is hypothesized to be initiated by the passage of a hard fecal bolus, resulting in a split in the epithelium of the anal canal. Along with poor vascular supply of the anal epithelium, increased activity (tone) of the internal anal sphincter smooth muscle further compromises the anodermal blood supply and contributes to the pain and ischemia of the anal epithelium, perpetuating ulceration and preventing healing.

In 2010, it was estimated by SDI Health LLC that there were approximately 1.1 million office visits per year for anal fissures.

About Ventrus

Ventrus is a development stage pharmaceutical company focused on the development of late-stage prescription drugs for gastrointestinal problems, specifically anal disorders. Our lead product is topical diltiazem (VEN 307) for the treatment of anal fissures for which the first Phase 3 trial was initiated in November 2010, and reported positive top line results in May 2012. The second Phase 3 trial began enrollment in the fourth quarter of 2012 and is ongoing. 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.

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; our anticipated capital expenditures, our estimates regarding our capital requirements, and our need for future capital; our reliance on our lead product candidate, VEN 307; 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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