



December 21, 2011

Ventrus BioSciences Completes Enrollment of Pivotal Phase 3 Trial of Diltiazem (VEN 307) in Patients With Anal Fissures

Expects to Deliver Top Line Results From Pivotal Trial in May-2012

NEW YORK, Dec. 21, 2011 (GLOBE NEWSWIRE) -- Ventrus BioSciences, Inc. (Nasdaq:VTUS) announced that S.L.A. Pharma has completed patient enrollment and randomization in the first Phase 3 clinical trial of Diltiazem (VEN 307) in patients with anal fissures. Initial top-line data from the Phase 3 study is expected to be available in May 2012. Ventrus Biosciences has licensed the North American rights to diltiazem hydrochloride cream from S.L.A. Pharma.

The Phase 3 diltiazem study is a randomized, double-blind, placebo-controlled trial to evaluate the safety and efficacy of diltiazem hydrochloride cream in subjects with anal fissure and is being conducted in 31 centers in Europe. The primary endpoint using an 11-point numerical pain rating scale (Likert-like scale) evaluates the change from baseline in the average of worst anal pain associated with or following defaecation for Week 4 (for the 7 treatment days immediately preceding the Week 4 visit). Consistent with the protocol for this trial, 465 patients have been randomized to diltiazem hydrochloride 2%, 4% cream, or placebo for 8 weeks of treatment, to be followed by a 4 week blinded observation period.

"Today the company reached an important milestone in the clinical development of diltiazem cream. We are grateful that our partner S.L.A. Pharma has completed the enrollment faster than we initially expected. We are very encouraged by the timeliness and the quality of the conduct of the trial to date and we look forward to the reporting of the data in May 2012," said Dr. Russell Ellison, Chairman and Chief Executive Officer of Ventrus BioSciences, Inc.

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 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 S.L.A. Pharma

S.L.A. Pharma is a privately held pharmaceutical company located outside Basel, Switzerland with an operations arm in the UK, which is focused solely on developing medicines for the prevention and treatment of gastrointestinal disorders including familial adenomatous polyposis, perianal Crohn's disease, opioid induced constipation, and anal fissures and faecal incontinence.

About Ventrus

Ventrus is a development stage specialty 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 hemorrhoids, for which the first Phase III clinical trial began in August 2011 and is ongoing, and topical diltiazem (VEN 307) for the treatment of anal fissures for which the first Phase III trial was initiated in November 2010, 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. 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.

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Source: Ventrus BioSciences

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