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Ventrus Biosciences Announces Results From Second Pivotal Phase 3 Trial of Diltiazem Cream (VEN 307) in Patients With Anal Fissure

- *VEN 307 efficacy as expected; placebo effect greater than anticipated, resulting in no significant difference between treatments*
- *Data demonstrate an excellent safety profile*
- *Company plans to request pre-NDA meeting with FDA to determine next steps*

NEW YORK, Feb. 12, 2014 (GLOBE NEWSWIRE) -- Ventrus Biosciences, Inc. (Nasdaq:VTUS) today announced top line efficacy and safety results from the second Phase 3 clinical trial of Diltiazem Hydrochloride 2% Cream (VEN 307) in patients with pain related to anal fissure (AF).

In this randomized double blind trial comparing diltiazem 2% cream versus placebo cream in 434 subjects in 90 centers globally, both treatment arms demonstrated a clinically meaningful improvement. The diltiazem 2% treatment arm demonstrated no significant improvement compared to placebo in the primary endpoint of average of worst anal pain associated with or following defecation. The mean of worst AF-related pain score at baseline was 7.09 for diltiazem 2% and 7.18 for placebo, decreasing to 3.81 (-3.28 difference) and 3.72 (-3.46 difference) respectively. Outcomes for the secondary endpoints of overall AF-related pain and PGI-I parallel the primary endpoint. Age, gender, and race were equivalent between arms, and results were not meaningfully different between countries.

Adverse events (AEs) were similar for the two treatment arms. Gastrointestinal disorders were the most common with 20.7% of patients in the diltiazem 2% arm versus 21.9% in the placebo arm, substantially less than reported in the first Phase 3 trial. Reports of headaches were 5.1% for diltiazem 2% and 1.9% for placebo. There was one serious adverse event of pregnancy.

In the first pivotal Phase 3 trial, the diltiazem 2% treatment arm demonstrated a statistically significant improvement compared to placebo in the primary endpoint of average of worst anal pain associated with or following defecation. The mean of worst AF-related pain score at baseline was 6.21 for diltiazem 2% and 6.38 for placebo, decreasing to 3.88 (-2.33 difference) and 4.35 (-2.03 difference) respectively (means not adjusted for baseline score).

"While this second study confirms a consistent effect in decreasing AF-related pain with diltiazem 2%, results among placebo patients are inconsistent across these two pivotal studies," said Dr. Russell Ellison, Chairman and Chief Executive Officer of Ventrus Biosciences, Inc. "Compounded diltiazem remains an important non-nitroglycerin treatment standard in this condition, yet this is an area which we believe may be more safely and reliably served by an FDA approved prescription pharmaceutical treatment. We look forward to discussing these results with the FDA."

Inasmuch as a primary purpose of this second Phase 3 trial was to complete the safety data package for a New Drug Application (NDA) with the FDA, Ventrus will request a pre-NDA FDA meeting to determine next steps in the program. 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.

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 characterized by severe anal pain associated with or after bowel movements. It is a common anal disorder, which we believe is underdiagnosed. 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. Topical diltiazem, which is not approved by the FDA as a use for anal fissure, is currently listed in the U.S. anal fissure treatment guidelines as a preferred agent prior to attempting surgery, and is available only as a compounded medicine.

About Ventrus

Ventrus is a specialty pharmaceutical company primarily focused on the development and commercialization of prescription drugs addressing gastrointestinal problems. The Company's lead product is topical diltiazem (VEN 307) for the treatment of anal fissures. Ventrus' product candidate portfolio also includes topical phenylephrine (VEN 308) intended to treat fecal incontinence. The Company has also recently licensed intellectual property and know-how relating to the oral delivery of bacteria, viruses and drugs to specific sites in the intestine, using a pH sensitive controlled release platform technology. The potential indication areas include (i) gastro-intestinal, auto-immune and metabolic disorders, (ii) viral and bacterial vaccines, and (iii) optimized colonic delivery of drugs.

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 components, 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 reliance on our lead product candidate, VEN 307; 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 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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