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Ventrus Biosciences Announces Poster Presentation on the Quality of Compounded Topical Diltiazem Hydrochloride Formulations for Anal Fissure at the American Pharmacists Association Meeting

Compounded Formulations From Retail Pharmacies Are Inaccurate in Respect to Potency Approximately 50% of the Time and Lack Content Uniformity Approximately 40% of the Time

NEW YORK, March 1, 2013 (GLOBE NEWSWIRE) -- Ventrus Biosciences, Inc. (Nasdaq:VTUS) today announced the poster presentation of the results from its study investigating the quality of compounded topical 2% diltiazem hydrochloride formulations for anal fissures at the American Pharmacists Association Meeting currently underway in Los Angeles.

The use of topical 2% diltiazem hydrochloride for treating anal fissures has been explored in multiple clinical trials since 2000. In 2004, the Standard Practice Task Force of the American Society of Colon and Rectal Surgeons (ASCRS) published revised practice parameters for managing anal fissure and stated that topical formulations of calcium channel blockers may be appropriately used to treat anal fissure and accorded this practice parameter the highest level of evidence and highest grade of recommendation. Because no commercially manufactured version of topical 2% diltiazem has been approved by the US Food and Drug Administration (FDA) for treatment of anal fissure, colon and rectal surgeons, gastroenterologists, and other physicians who want to follow ASCRS practice parameters have to write prescriptions for a product that will be extemporaneously compounded by retail pharmacies. To examine the quality of compounded formulations of topical 2% diltiazem, Ventrus undertook a high-performance liquid chromatography (HPLC) analysis of preparations gathered from retail pharmacies in a metropolitan region.

A participating healthcare professional wrote 12 prescriptions, with 2 refills allowed per prescription, so that 3 prescriptions could be filled at each of 12 pharmacies (36 total refills) for compounded 2% diltiazem cream. The analysis included an assessment of potency (percentage of claim) and content uniformity, with sampling from 8 different pre-specified locations within the compounded formulation containers.

The United States Pharmacopoeia (USP) standard for potency is 90% to 115% of claim. Of the 36 preparations, 5 (13.89%) were supra-potent and 13 (36.11%) were sub-potent. The supra-potent prescriptions ranged in potency from 117.2% to 128.5% of claim, and the sub-potent prescriptions ranged in potency from 34.8% to 89.8% of claim. Fourteen (38.9%) preparations lacked content uniformity according to the USP standard.

"These results demonstrate that although compounded drugs might be formulated under professional pharmacy standards, these standards are inherently less rigorous than federal GMP quality standards," said Russell H. Ellison, M.D., M.Sc., Chairman and Chief Executive Officer of Ventrus Biosciences, Inc. "Clearly, a topical 2% diltiazem cream produced under GMP regulations is needed to avoid the large percentage of substandard compounded formulations of a drug specifically recommended by the practice parameters of a medical society."

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 Biosciences

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: our ability to complete the offerings, including the satisfaction of the closing conditions for each offering; the estimated proceeds from each offering and our use of the anticipated proceeds from the offerings; 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; 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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