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Ventrus Biosciences Receives Date for Type B Pre-NDA Meeting With FDA for DOLIZEM (Diltiazem Hydrochloride Cream) in Anal Fissures

NEW YORK, April 4, 2014 (GLOBE NEWSWIRE) -- Ventrus Biosciences, Inc. (Nasdaq:VTUS), a pharmaceutical company focused on developing and commercializing gastrointestinal products, today announced that, in response to a request from the company, the U.S. Food and Drug Administration (FDA) has scheduled a Type B pre-NDA meeting on Thursday, June 19, 2014 at which the company will seek guidance on its planned new drug application (NDA) for DOLIZEM (diltiazem hydrochloride cream) in anal fissures. Ventrus would expect to file an NDA in the second half of 2014 with an anticipated PDUFA date in the second half of 2015 if there is a positive outcome of this pre-NDA meeting.

About DOLIZEM (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 is believed to be 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 DOLIZEM for the treatment of anal fissures. 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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