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Ventrus Hires inVentiv Clinical Solutions and Almac Group for Its Phase III Pivotal Trial in the Treatment of Hemorrhoids With Iferanserin Ointment

NEW YORK, March 3, 2011 (GLOBE NEWSWIRE) -- Ventrus Biosciences, Inc. (Nasdaq:VTUS), a pharmaceutical company focused on developing and commercializing gastrointestinal products, today announced that it has selected inVentiv Clinical Solutions to manage its Phase III pivotal trial with Iferanserin and Almac Group to provide electronic patient-reported outcomes solutions.

inVentiv Clinical has supported 118 gastrointestinal studies in Phase II and 501 gastrointestinal studies in Phase III totaling over 12,000 patients. In its 25 years in business, inVentiv Clinical has submitted 30 NDAs and currently employs 850 FTE's.

Almac's technologies have been deployed in over 1600 clinical trials, incorporating over 1.6 million patients in over 80 countries, and more than 60 languages.

CEO Russell Ellison commented on the selection of inVentiv and Almac: "During our selection process, we were looking for strategic partners who have a proven track record with gastrointestinal studies and track record of success. inVentiv and Almac rose above the other research organizations and we are delighted to be working with them."

Ventrus plans to initiate its first Phase III pivotal trial in 2011 and expects to be able to report data in the first quarter 2012. The study is currently planned to enroll 400 patients, who will be randomized 1:1 to placebo ointment or Iferanserin, to be applied intra-anally, twice daily. The primary endpoint is expected to be cessation of bleeding.

About Ventrus

Ventrus is a development stage specialty pharmaceutical company focused on the development of late-stage prescription drugs for gastrointestinal disorders. Our lead product, Iferanserin (VEN 309) is a new chemical entity, or NCE, for the topical treatment of hemorrhoids, which targets a specific serotonin receptor (5HT2A) thought to be important in the disease. The first late phase clinical trial (Phase III) with Iferanserin is expected to start mid-year 2011 and we expect data to be available in the first quarter of 2012

Our additional product candidate portfolio consists of two in-licensed late-stage drugs intended to treat anal fissures (VEN 307) and fecal incontinence (VEN 308). The first Phase III clinical trial with VEN 307 has begun in Europe and we expect data to be available in the second quarter of 2012. These candidates are two molecules that were previously approved and marketed for other indications and that have been formulated into our 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 retain and hire necessary employees and to staff our operations appropriately; 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 cost, timing and results of clinical trials and other development activities involving our product candidates; our anticipated capital expenditures and our estimates regarding our capital requirements; 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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