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Aviragen Therapeutics Announces Top-Line Results from Phase 2b SPIRITUS Trial of Vapendavir

ATLANTA, Feb. 13, 2017 (GLOBE NEWSWIRE) -- Aviragen Therapeutics (NASDAQ:AVIR), a company focused on the discovery and development of the next generation of direct-acting antivirals to treat infections that have limited therapeutic options, today announced top-line data from its Phase 2b SPIRITUS trial, a multi-center, randomized, double-blind, placebo-controlled, dose-ranging study of vapendavir in moderate to severe asthmatics with a rhinovirus (RV) infection. Vapendavir did not demonstrate a statistically significant reduction in the asthma control questionnaire-6 (ACQ-6) at day 14, the primary endpoint, for either the 264 mg or 528 mg cohorts compared to placebo.

"We are disappointed that the SPIRITUS trial did not meet its primary endpoint in this patient population. There was evidence of an antiviral effect in patients that received vapendavir within the first day following the onset of their symptoms, and as such, we plan to take time to fully analyze the data before making a decision on whether to initiate a study in hematopoietic stem cell transplant patients, where the ability to stop the progression of the RV infection could be beneficial," stated Joseph Patti, PhD, President and Chief Executive Officer of Aviragen. "We are sincerely grateful for the patients, investigators and staff that participated in the trial."

The Phase 2b SPIRITUS clinical trial of vapendavir was conducted at approximately 68 sites in North America and Europe. Patients aged 18-70 years that had an established history of moderate-to-severe asthma and a history of losing asthma control as a result of an upper respiratory tract infection were eligible for enrollment. The intent-to-treat (ITT) patient population consisted of 455 randomized patients and from this group there were 168 laboratory-confirmed HRV-infected patients (ITT-infected; ITT-I).

- **Primary Endpoint Data**: Subjects that received 264 mg (n=54) or 528 mg (n=57) vapendavir had a least square means change in ACQ-6 at day 14 of -0.75 and -0.79, respectively, compared to placebo of -0.94 (n=57). A 0.5 point change in ACQ-6 is considered clinically relevant. The improvement of ACQ-6 in the placebo cohort was larger than expected for this patient population.

- **Secondary Endpoint Data**: The results of the SPIRITUS study demonstrated statistically significant antiviral effects for patients that received vapendavir within 24 hours of first symptoms, consistent with previous studies. Secondary endpoints evaluating the lung function measure FEV1 and reduction in asthma exacerbations did not show significant differences between the treatment groups and placebo.

- **Safety Data**: Vapendavir was shown to be generally well tolerated and the safety profile was consistent with previous clinical studies.

About Aviragen Therapeutics

Aviragen Therapeutics is focused on the discovery and development of the next generation of direct-acting antivirals to treat infections that have limited therapeutic options and affect a significant number of patients globally. The Company has four Phase 2 clinical programs: vapendavir, an oral treatment for rhinovirus (RV) upper respiratory infections in moderate-to-severe asthmatics; vapendavir for the treatment of RV infections in hematopoietic stem cell transplant patients; BTA585, an oral fusion protein inhibitor in development for the treatment of respiratory syncytial virus infections; and BTA074, a topical antiviral treatment for condyloma caused by human papillomavirus types 6 & 11. For additional information about the Company, please visit www.aviragentherapeutics.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve known and unknown risks and uncertainties concerning Aviragen Therapeutics' business, operations and financial performance. Any statements that are not of historical facts may be deemed to be forward-looking statements, including the timing of our plan to provide more clarity on whether a clinical trial will be initiated in hematopoietic stem cell transplant patients. Various important factors could cause actual results, performance, events or achievements to materially differ from those expressed or implied by forward-looking statements, including: the Company, the U.S. Food and Drug Administration (FDA) or a similar regulatory body in another country, a data safety monitoring board, or an institutional review board delaying, limiting, suspending or terminating the clinical development of any of the Company's product candidates at any time for a lack of efficacy, safety, tolerability, regulatory or manufacturing issues, or any other reason

whatsoever; the Company's ability to secure, manage and retain qualified third-party clinical research, data management and contract manufacturing organizations upon which it relies to assist in the design, development, implementation and execution of the clinical development of all its product candidates and those organizations' ability to successfully execute their contracted responsibilities; the Company's ability to comply with applicable government regulations in various countries and regions in which we are conducting, or expect to conduct, clinical trials; and other cautionary statements contained elsewhere in this press release and in our Annual Report on Form 10-K and our other reports filed with the Securities and Exchange Commission. There may be events in the future that the Company is unable to predict, or over which it has no control, and the Company's business, financial condition, results of operations and prospects may change in the future. The Company may not update these forward-looking statements more frequently than quarterly unless it has an obligation under U.S. Federal securities laws to do so.

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