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Aviragen Therapeutics Provides Update on Phase 2a Trial of BTA585 for the Treatment of RSV Infections

ATLANTA, May 26, 2016 (GLOBE NEWSWIRE) -- Aviragen Therapeutics, Inc. (NASDAQ:AVIR) (formerly Biota Pharmaceuticals, Inc.), a pharmaceutical company that is developing the next generation of antivirals, today announced that it has voluntarily decided to delay further enrollment in the Phase 2a trial of BTA585 for the treatment of RSV infections being conducted in the U.K. This decision emanated from a lab report from one subject showing an increase of a cardiac enzyme level coupled with transient ECG changes, which led to a hospitalization of less than 24 hours. The subject's ECGs were normal prior to hospitalization and the cardiac enzyme levels returned to baseline shortly thereafter.

The Company also reported that subsequent to the submission of the requisite safety report to the regulatory authorities, it received verbal communication from the U.S. Food and Drug Administration (FDA) that the investigational new drug application (IND) for BTA585 has been placed on clinical hold for studies being conducted in the U.S. under the IND. There are currently no trials of BTA585 being conducted under the IND. More specific written information from the FDA concerning the clinical hold is expected within 30 days.

"Patient safety is paramount to us, which led to our decision to voluntarily delay enrollment. We have proactively reached out to the Medicines and Healthcare Products Regulatory Agency (MHRA), the regulatory authority in the U.K., to discuss this event and any implications it may have on the continued clinical development of BTA585," said Joseph M. Patti, PhD, President and Chief Executive Officer of Aviragen Therapeutics.

About Aviragen Therapeutics, Inc.

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 three product candidates in active clinical development: These include vapendavir, an oral treatment for human rhinovirus upper (HRV) respiratory infections in moderate-to-severe asthmatics currently being evaluated in the Phase 2b SPIRITUS trial; BTA585, an oral fusion protein inhibitor that has received Fast Track designation by the U.S. FDA, in Phase 2 development for the treatment and prevention of respiratory syncytial virus (RSV) infections; and BTA074, a topical antiviral treatment in Phase 2 development 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 receiving written information from the U.S. Food and Drug Administration (FDA). 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 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 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, Quarterly Report on Form 10-Q 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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