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Aviragen Therapeutics Resumes Enrollment in Phase 2a RSV Challenge Trial

ATLANTA, July 12, 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 it is resuming enrollment in its Phase 2a challenge study of BTA585, an oral fusion inhibitor in development for the treatment and prevention of respiratory syncytial virus (RSV) infections.

"We are pleased to have received approval from the MHRA to continue the Phase 2a challenge study of BTA585. The decision was based on our submission of all requested information and documentation and the subsequent review by the UK regulatory authority. We continue to anticipate completing the trial by the end of 2016," said Joseph M. Patti, Ph.D., President and Chief Executive Officer of Aviragen Therapeutics.

In addition to receiving MHRA and Ethics Committee approval to resume enrollment and dosing in the Phase 2a trial, the Company also reported that it has received written confirmation from the U.S. Food and Drug Administration (FDA) of the previously announced clinical hold of the investigational new drug (IND) application for BTA585. The Company plans to submit a complete response to the FDA by the first quarter of 2017, including requested data from additional rodent studies.

The double-blind, placebo-controlled, Phase 2a trial is designed to evaluate the safety, pharmacokinetics, and antiviral activity of orally-dosed BTA585 in healthy volunteers challenged intranasally with RSV. The primary endpoint of the study is area under the curve for the viral load in nasal wash among subjects who test positive for RSV prior to dosing.

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: 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. 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 timing of completing the Phase 2a RSV challenge study, the timing of submitting a complete response to the clinical hold to the FDA, 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.

Contacts:

Mark Colonnese

Executive Vice President and Chief Financial Officer

Aviragen Therapeutics, Inc.

(678) 221-3381

mcolonnese@aviragentherapeutics.com

Beth DelGiacco

Stern Investor Relations, Inc.

(212) 362-1200

beth@sternir.com

Primary Logo

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