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Aviragen Therapeutics Announces Top-Line Results from Phase 2a RSV Challenge Study of BTA585

ATLANTA, Feb. 01, 2017 (GLOBE NEWSWIRE) -- Aviragen Therapeutics, Inc. (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 double-blind, placebo-controlled Phase 2a study of BTA585 in adults challenged intranasally with respiratory syncytial virus (RSV). The data indicate there was not a significant reduction in the primary endpoint, which was viral load. The overall safety profile of BTA585 was favorable and consistent across treatment groups.

"We're in the early stages of assessing the available data from the study. On a positive note, there were no safety signals observed for BTA585 compared to placebo. We also observed biological activity in several of the endpoints, however, the considerable variability in viral load among the cohorts and the small number of subjects that became infected with RSV likely impacted the ability to detect a significant difference between the groups," commented Joseph M. Patti, PhD, President and Chief Executive Officer of Aviragen Therapeutics. "We plan to analyze the full data set once it becomes available and communicate our plan for this program in the second quarter of 2017."

The Phase 2a trial was designed to evaluate the safety, pharmacokinetics, and antiviral activity of BTA585, an orally-dosed fusion inhibitor, in adult volunteers infected intranasally with RSV. The Phase 2a study randomized three cohorts of 20 healthy adults who received either 400 mg BTA585, 600 mg BTA585 or placebo dosed twice a day for seven days. The primary endpoint was viral load from first dose of study drug through day 12 measured by area under the curve (AUC; least square means $\log_{10}$ copies/mL*hours). Key secondary endpoints included the severity of RSV disease as measured by 10 RSV-related clinical symptoms and mucus weight.

- Subjects receiving 400 mg (n=13) or 600 mg (n=12) BTA585 had least square means for viral loads of 484.6 and 534.9, respectively, compared to the placebo viral loads of 552.9 (n=13).
- The least square means AUC for RSV-related clinical symptom scores was 162.1 for the 400 mg cohort and 244.3 for the 600 mg cohort, compared to 318.1 for the placebo cohort. It should be noted that only 9 of 13 placebo patients reported any symptoms during the study period.
- Subjects receiving 400 mg, 600 mg, or placebo had total mucus weights of 8.4 g, 15.5 g, and 16.8 g, respectively.

BTA585 demonstrated a favorable safety profile across both treatment groups. The overall incidence of treatment-emergent adverse events was very similar across placebo and active treatment arms. There were no adverse events or laboratory abnormalities that led to treatment discontinuation. Adverse events that were more common with BTA585 treatment compared to placebo and occurred in more than two BTA585-treated subjects were chromaturia (urine discoloration), epistaxis (nose bleed), abdominal discomfort, and upper respiratory infection. There was one serious treatment-emergent adverse event of an increased cardiac enzyme in the 400 mg cohort, which was previously reported. There were no clinically meaningful adverse trends in vital signs, clinical safety chemistry or hematology laboratory results.

About Respiratory Syncytial Virus (RSV)

RSV is a major cause of acute upper (colds) and lower (pneumonia and bronchiolitis) respiratory tract infections in infants, young children, and adults. Each year in the United States, RSV accounts for an estimated 2.1 million medical visits in children under the age of five, with many of the children afflicted requiring hospitalization. At the present time there is no effective vaccine to prevent or recommended therapy to treat RSV infections.

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 is also being evaluated 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 announcing our plans for the next steps in the development of BTA585. 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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