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**ALPHAVAX ANNOUNCES INITIAL ANALYSIS OF DATA  
FROM CMV PHASE 1 CLINICAL TRIAL**

**Research Triangle Park** - AlphaVax, Inc. announced today an initial analysis of data from a Phase I clinical trial of a cytomegalovirus (CMV) vaccine that is based on its platform alphavirus replicon vector technology.

The trial is a placebo-controlled, randomized, double-blind, single center study involving 40 healthy, 18-40 year old, CMV-negative volunteers. The trial is being conducted by David I. Bernstein, M.D., Director of Infectious Diseases at the Cincinnati Children's Hospital Medical Center in Ohio. AlphaVax's CMV vaccine was administered three times over six months at one of two dosage levels, and safety and immunogenicity data were obtained from all volunteers following each dose of the vaccine. Confirming AlphaVax's earlier reported experience in humans with its prototype HIV and influenza vaccine candidates, the CMV vaccine has proven to be safe and very well tolerated. While the study remains blinded, it is clear that a majority of the subjects developed substantial antibody or T cell responses to all three CMV antigens in the vaccine. Preliminary results suggest that both the CD4 and CD8 cells appear to be multifunctional T cells, similar to the type that has recently been associated with protective responses.

"We are very pleased with these results as they clearly demonstrate the vaccine's ability to stimulate readily detectable immune responses to all three vaccine-expressed antigens and at both dosage levels. It is these types of responses, both cellular and humoral, that will be required for an effective vaccine against CMV infection and disease." said Dr. Robert Olmsted, Vice President of Research.

The vaccine used in this trial is bivalent as it contains two replicon vectors which are derived from an attenuated alphavirus. One replicon vector expresses the pp65 and IE1 genes of CMV and the second the CMV gB glycoprotein gene. Virus-like particles containing the replicon vectors were produced in cell culture, harvested and administered to the volunteers at two dosage levels. A key design and safety feature of this single-cycle vaccine technology is that there is no further replication of the virus-like particles after the expression of the CMV proteins in the vaccine recipients.

#### **About CMV**

CMV is a herpesvirus that is a major cause of morbidity and mortality in congenitally infected infants and hematopoietic stem cell (HSCT) and solid organ transplant (SOT) recipients. Congenitally acquired CMV, the most common congenital infection in the United States, causes occasional mortality and significant morbidity in infants and young children (e.g., hearing loss and mental retardation). For healthy people who acquire CMV after the prenatal period, infection is life-long but typically asymptomatic. However, CMV reactivation or primary infection in HSCT and SOT recipients with suppressed or impaired immune systems can be life-threatening. In these patients, CMV infection is a major cause of disease, organ rejection, and death, with mortality rates among infected HSCT patients of 50% despite current anti-CMV drugs. Manifestations of CMV include pneumonia, hepatitis and gastrointestinal disease, usually occurring within the first 100 days after transplant.

**About AlphaVax**

AlphaVax, Inc. is a North Carolina-based, clinical-stage company that uses a novel alphavirus vector platform technology that has proven to be highly flexible and immunogenic, and allows the same manufacturing, formulation, and delivery strategies to be applied to many different products. The company employs staff with expertise spanning vaccine design, process development, GMP manufacturing, quality assurance, and regulatory and clinical affairs. In addition to cytomegalovirus, important disease targets include influenza, cancer, HSV, RSV, and a number of biodefense vaccine products. The AlphaVax headquarters and R&D facilities are located in Research Triangle Park, and its GMP manufacturing facility is located in Lenoir, NC.

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