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ALPHAVAX ANNOUNCES RESULTS FROM INITIAL TESTING OF ITS H1N1 (SWINE) INFLUENZA VACCINE

Research Triangle Park, NC - AlphaVax, Inc. announced today that it has completed process development and preclinical immunogenicity studies of its H1N1 (swine) influenza vaccine and will manufacture clinical trial material by the end of the month. This vaccine has shown good production yields as well as excellent immunogenicity, even after just a single inoculation.

“Our vaccine platform provides several potential advantages over other influenza vaccine approaches in that vaccines can be rapidly constructed and tested, and are produced in cell culture systems rather than eggs. In addition, our vaccines do not require the use of an adjuvant, and they raise not only strong antibody responses but robust cellular responses, both of which could be important in the face of a developing pandemic where there are several variant virus forms circulating” said Jonathan Smith, AlphaVax’s Chief Scientific Officer.

The studies performed at AlphaVax utilized the California 04/2009 HA sequence obtained from the WHO GISAID database on April 25th. Mice inoculated with the AlphaVax H1N1 vaccine showed strong dose-dependent hemagglutination inhibition (“HI”) antibody responses. After just a single dose of the H1N1 vaccine, all vaccinated animals developed HI antibody levels considered to be protective. These responses were boosted approximately 8-fold by a second dose given three weeks later. Responses measured by ELISA and ELISPOT assays, which assess antibody and T cell responses, respectively, mirrored the HI responses. The design of future clinical trials of this vaccine will be based on two previous successful influenza vaccine trials run by AlphaVax, one carried out in healthy young adults and the other in an elderly population.

According to Andrew Graham, AlphaVax’s Vice President for Development and Technical Operations, “AlphaVax will begin GMP-compliant manufacturing of this vaccine for clinical testing next week, which is less than three full months from our initial receipt of the gene sequence from the WHO. We are currently scaling up the process used to manufacture VRP vaccines and anticipate yields up to 1 million doses of pandemic influenza vaccine per lot at the 1,000 L bioreactor scale. Since the process is performed predominantly in disposable equipment, the design, construction and validation of a facility leading to the production of product for the market would be 1-2 years less than for a typical vaccine manufacturing facility.”

About AlphaVax

AlphaVax, Inc. is a North Carolina-based, clinical-stage company that uses a proprietary 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’s business strategy is to maximize the potential of this platform through a mixture of in-house and partnered programs. The AlphaVax technology is currently being used to advance vaccines for cytomegalovirus, herpes simplex virus, respiratory syncytial virus, a range of cancers, influenza, HIV and a number of biodefense targets. The AlphaVax headquarters and R&D facilities are located in Research Triangle Park, and its GMP-compliant manufacturing facility is located in Lenoir, NC.

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