

AlphaVax Begins Human Clinical Trials of Novel Vaccine Technology

RESEARCH TRIANGLE PARK, N.C. - AlphaVax, Inc. today announced the beginning of the first human trials of a vaccine using the company's novel **ArVtm** vaccine technology, which has been employed to develop a new vaccine for HIV that is now starting clinical trials in the United States and South Africa.

"The initiation of clinical trials with our technology marks a very exciting milestone not just for those working on HIV vaccines but for the entire vaccine field," said Peter Young, president & CEO of AlphaVax. "This kind of novel technology has the potential to reshape the vaccine marketplace, and it is very gratifying to demonstrate that we can translate this state-of-the-art science into products whose promise can be tested and advanced in the clinic."

The **ArVtm** vaccine technology has generated particular scientific interest because of its apparent ability to target the immune system and elicit broad-based immune responses, including significant cellular immunity thought to be critical to successful immune protection against many challenging diseases, like HIV, that have so far defeated vaccine development efforts.

The technology utilizes a non-propagating form of an alphavirus vector that has been engineered to express genes from disease-causing pathogens or cancers. In many preclinical disease models, vaccines using this technology have generated a beneficial immune response that prevents or controls the target disease. The technology has potentially very broad applications across a wide range of infectious diseases and cancers for which there are either poor or no existing vaccine-based medical interventions.

The **ArVtm** clinical trial will evaluate the technology's safety and immune potential using an HIV gene from the subtype of the virus that is prevalent in South Africa. The trial will involve 48 non-HIV infected participants in each country at four different dose levels using a double-blind, placebo-controlled design.

The trial is being conducted by the HIV Vaccine Trials Network (HVTN), which is funded and supported by the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH). The HVTN is a global clinical trials network established by NIAID to expedite clinical evaluation of HIV vaccine candidates.

"We are pleased to be able to bring the expertise of our clinical trials network to the further investigation of the AlphaVax technology," stated Larry Corey, the HVTN's principal investigator. "A vaccine for HIV is one of the world's most pressing medical needs, and it is exciting to apply strong new ideas in the vaccine field to HIV vaccine development."

The HIV vaccine product using the AlphaVax technology, designated AVX101, has involved an unusually extensive international collaboration including AlphaVax, the Division of AIDS at the NIAID and the NIAID-sponsored HIV Vaccine Trial Network, the University of North Carolina in Chapel Hill, and four groups in South Africa: the University of Cape Town, the National Institute for Communicable Diseases, the Medical Research Council, and the South African AIDS Vaccine Initiative. NIAID and IAVI, the International AIDS Vaccine Initiative, also provided support for the early development of this candidate vaccine.

"The contributions, support, and commitment of many collaborators," said Don Burke, M.D., professor of public health at Johns Hopkins University and principal investigator for the trial, "have helped put AlphaVax in a position to pilot this novel technology in the development of an HIV vaccine. In the process, we are advancing a possible vaccine solution for a disease that infects 16,000 people every day, most of them under 25, and at the same time learning how to apply a complex new technology to other significant diseases."

No live HIV is used in the manufacturing of the vaccine candidate, so there is no way for the vaccine candidate to cause HIV infection, Dr. Burke further noted. Trial participants are being counseled periodically through the course of the trial to reduce risk behavior.

Trial sites involved in the study include Johns Hopkins, Columbia University, Vanderbilt University, and the University of Rochester in the United States. In South Africa, the sites are at the University of Witwatersrand at the Chris Hani Baragwanath Hospital in Soweto and the Medical Research Council in Durban.

The **ArV**tm vaccine technology is currently in active development as a vaccine for many other diseases, said Young. These include different forms of cancer, like prostate and breast cancer as well as infectious diseases like herpes. This work is being pursued both at AlphaVax and with corporate, government, and academic partners.

About the HIV Vaccine Trials Network

The HIV Vaccine Trials Network is a partnership of investigators, clinical trial sites, and community representatives working with industry and governments in the global search for a preventative HIV vaccine. Funded through the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH) an agency of the Department of Health and Human Services, the HVTN conducts all phases of clinical trials, from evaluating candidate vaccines for safety and the ability to stimulate immune responses, to testing vaccine efficacy. Headquartered at the Fred Hutchinson Cancer Research Center in Seattle, Washington, the HVTN at present includes 25 research sites on four continents. For more information, please visit www.hvtn.org.