

EMORY

HealthNews

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New Clinical Trial Begins for HIV/AIDS Vaccine Developed at Emory and GeoVax

A new human clinical trial will begin this month at several sites around the country testing both components of an HIV/AIDS vaccine developed by a team of researchers at the Yerkes National Primate Research Center of Emory University, GeoVax, Inc., and the Emory Vaccine Center, along with colleagues at the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC).

The vaccine uses a two-part DNA prime-boost strategy developed by a scientific team led by Harriet Robinson, PhD, chief of microbiology and immunology at the Yerkes Research Center, a faculty member of the Emory Vaccine Center, and chief of the GeoVax, Inc. Scientific Advisory Board.

The vaccine includes two inoculations of a DNA vaccine that primes the immune system to recognize HIV and two doses of subsequent booster vaccine based on a recombinant MVA poxvirus. The vaccine produces the three major proteins expressed by HIV and is expected to induce the immune system to respond to these distinguishing features of HIV should the actual virus appear. Neither component of the vaccine incorporates the complete intact HIV virus.

As reported in *Nature Medicine* in 1999 and in *Science* in 2001, a prototype of this vaccine was successful in containing a challenge virus and preventing progression to AIDS in nonhuman primates.

The vaccine technology was licensed to GeoVax, Inc., a company founded by Dr. Robinson, GeoVax President/CEO Don Hildebrand, Emory University and the Emory Vaccine Center to further develop, manufacture, test and evaluate the vaccine.

In 2003, a prototype DNA vaccine was tested in a group of HIV-negative volunteers to evaluate safety. This Phase I human trial was conducted through the HIV Vaccine Trials Network (HVTN). Based on these successful studies, a new GeoVax Investigational New Drug application recently received approval by the U.S. Food and Drug Administration to proceed with additional clinical

trials to test the two components of the vaccine in a prime/boost protocol.

Beginning this month, human clinical trials will evaluate the DNA and MVA components of the vaccine in HIV-negative volunteers at several U.S. sites in the HIV Vaccine Trials Network, including the University of Alabama at Birmingham, Saint Louis University, the University of Maryland, and Vanderbilt University. The HVTN is funded and supported by the National Institute of Allergy and Infectious Disease (NIAID) of the NIH.

This trial will have two phases. The first phase will be a dose escalation to evaluate safety and immune responses. Initially, low doses of the two vaccine components will be given to 12 volunteers. If the vaccine proves safe, the vaccine will then be tested at high dose in 36 volunteers. If the vaccine proves safe and shows good immunogenicity in the dose/escalation studies, a second phase of clinical testing will be initiated. In this phase, 72 volunteers will be used to conduct the initial studies on optimizing the dosing schedule.

Emory University's Woodruff Health Sciences Center is one of the nation's pre-eminent academic health centers, devoted to Making People Healthy through research, teaching, and patient care. It includes the Emory University School of Medicine, the Rollins School of Public Health, the Nell Hodgson Woodruff School of Nursing, and the Yerkes National Primate Research Center. Its clinical arm is Emory Healthcare, Georgia's largest and most comprehensive health care system, consisting of Emory University Hospital, Emory Crawford Long Hospital, Wesley Woods Center, The Emory Clinic, the Emory Children's Center, EHCA, LLC, Emory-Adventist Hospital, and other affiliates.

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