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AIDS Vaccine Developed At Emory And The NIH Moves To Clinical Trials

ScienceDaily (Jan. 24, 2003) — A vaccine aimed against AIDS, developed at the Yerkes National Primate Research Center of Emory University, the Emory Vaccine Center, and the Laboratory of Viral Diseases at the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH), will begin a Phase I clinical trial this week.

A total of 30 human volunteers will be enrolled at the University of Alabama at Birmingham, the University of Washington in Seattle, and the San Francisco Department of Public Health. The trial is funded by NIAID and is conducted by the HIV Vaccine Trials Network, located at the Fred Hutchinson Cancer Research Center in Seattle, Wash.

Developed by virologists Harriet L. Robinson, PhD, James M. Smith, PhD, Bernard Moss, MD, PhD, and Linda Wyatt, PhD, the vaccine strategy employs two different components: two inoculations of a DNA vaccine that primes the immune system to recognize HIV; and a subsequent booster vaccine based on a recombinant poxvirus. Neither component incorporates the actual virus; instead, the vaccine produces the three major proteins expressed by HIV. In essence, the vaccine induces the immune system to respond to the distinguishing features of HIV so the system will respond to the actual virus should it appear.

This first clinical trial, which will last one year, will focus on assessing the safety of the DNA primer vaccine among HIV-negative volunteers, who will be randomly assigned to receive one of the following: high-dose vaccine, low-dose vaccine, or placebo. A second, separate clinical trial will focus on the safety of the booster vaccine.

"We will have a third Phase I trial to test the combined regimen of the DNA and booster portions of the vaccine strategy," said Dr. Robinson, who is chief of the Yerkes Division of Microbiology and Immunology and a faculty member of the Emory Vaccine Center. As Robinson and her colleagues reported in Science in 2001, in a study involving 24 rhesus macaque monkeys, the prime-boost vaccine strategy successfully contained infection and prevented progression to AIDS. According to a subsequent Yerkes study reported in October 2002 in the Journal of Virology, levels of viral RNA and DNA in the monkeys have declined to the nearly undetectable levels characteristic of a small subset of HIV-infected people, termed long-term non-progressors, who are infected with HIV but do not develop AIDS.

"It is important to remember that this clinical trial represents the culmination of years of work in basic science and preclinical studies involving animal models that have greatly expanded our knowledge of immunology," said Vaccine Center Director Rafi Ahmed, PhD. "Every new AIDS vaccine candidate that enters human studies brings us closer to understanding HIV and the human immune system – and to ending the worldwide AIDS pandemic."

The experimental vaccine is licensed from Emory by GeoVax, Inc., a company founded by Emory

University and the Emory Vaccine Center to manufacture the vaccine.