PRESS RELEASE
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AIDS Research Alliance Commences New HIV Vaccine Trial in Los Angeles

(LOS ANGELES, CA) AIDS Research Alliance of America (ARA), in collaboration with UCLA, launched the latest HIV vaccine study in Los Angeles today. As part of the National Institutes of Health (NIH)-funded HIV Vaccine Trials Network (HVTN), AIDS Research Alliance is one of 14 sites throughout the US to begin testing a new prime-boost HIV vaccine that may provide valuable insight into how to better control HIV infection.

The Basics of HVTN 505

The NIH-funded HVTN 505 is a Phase 2, proof-of-concept study that employs a prime-boost strategy of two investigational vaccines developed by scientists at National Institutes of Health's Vaccine Research Center (VRC). Study volunteers will be vaccinated with either (a) a recombinant DNA-based vaccine (the primer vaccine) over the course of eight weeks followed by a single immunization with a recombinant boosting vaccine, or (b) placebos at the same intervals.

The primary study objective is to see if the prime boost vaccine can significantly reduce the amount of virus (called 'viral load') in individuals who become infected with HIV. This is important because viral load is a marker of potential vaccine effect on disease progression, and therefore, a signal of potential vaccine efficacy. An HIV vaccine that lowers viral load may also delay the onset of illness, even if it doesn't prevent HIV infection, and may also reduce transmission of the virus to others.

Neither of the two vaccines contains HIV and neither vaccine can infect study participants with the virus. Both vaccines have been found safe when tested in hundreds of people in earlier clinical trials.

Why This Study?

Dr. Stephen J. Brown, Medical Director at AIDS Research Alliance, states, "For every two people put on HIV drugs, there are seven new infections. The virus continues to outpace our ability to fight it and vaccines have historically been the best tool for stopping infectious diseases of this magnitude. We have been part of the quest to find an HIV vaccine for more than a decade, and we are excited to continue to help move the science forward through this important study."

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HIV has proven itself to be a challenging virus to vaccinate against during the more than two decades of HIV vaccine research efforts. It is believed that the results of HVTN 505 will provide a clearer picture of the pathway to a successful vaccine, particularly in light of the fact that for HIV, no animal model can clearly predict the results found in humans.

“This study represents a step forward in defining the immune response needed to control HIV infection," explained Dr. Judith S. Currier, Associate Director of the UCLA Clinical AIDS Research and Education Center (CARE). "Because it is not anticipated that this vaccine candidate will prevent HIV infection, it is not being studied for FDA approval. While this strategy is a departure from previous HIV vaccine clinical trials, the study will bring powerful information to better focus future efforts to design and test vaccine candidates. For example, if this regimen is shown to lower HIV viral load, it will be an indication of promise for the development of T-cell-based vaccines, and may also provide information on what specific T-cell responses are most beneficial."

Dr. Brown stated, “Safety is always our top priority, and the design of HVTN 505 reflects this.” Key safety considerations built into this study include:

- The vaccine used in this study *cannot* cause HIV infection.
- All participants will receive the best available prevention services, including risk reduction assessment and counseling, condoms, and access to local prevention services.
- The protocol team for this study includes HVTN study investigators and study site staff, among them clinic coordinators, community educators and Community Advisory Board members, as well as staff from the Division of AIDS, part of NIAID.

The NIH-funded HVTN 505 trial will enroll 1350 HIV-negative men between the ages 18 to 45 who have sex with men (MSM). The trial will be conducted in trial sites located in 12 cities across the US. As a clinical research site of the UCLA CARE Center's AIDS Prevention and Treatment Clinical Trials Unit, AIDS Research Alliance is the only HVTN 505 trial site in Southern California.

In light of the modest success reported from recent Thai vaccine trial – which also used a prime-boost strategy – AIDS Research Alliance and UCLA are eager to move the science forward. “The Thai trial is an important contributor towards the mosaic of HIV vaccine research. HVTN 505 will continue this endeavor and will help us move the entire field forward,” states Carolyn Carlburg, JD, President and CEO of AIDS Research Alliance.

For more information on the study, please visit www.hopetakesaction.org.

About AIDS Research Alliance of America (ARA)

Founded by physicians and activists 20 years ago, AIDS Research Alliance of America is our nation's only not-for-profit, community-based AIDS research organization pioneering new treatment strategies at the forefront of HIV science. Injecting urgency and innovation into the field of HIV science, AIDS Research Alliance exists outside the traditional biomedical establishment to develop more effective treatments, to find new ways to stop the spread of HIV, and ultimately—our vision—to find a cure for AIDS. AIDS Research Alliance has conducted over 120 clinical and pre-clinical studies, ranging from therapies that employ a holistic approach to HIV care to the first ever in-human HIV vaccine trial. In this way, AIDS Research Alliance of America has "fast-tracked" to market nearly half of all existing anti-HIV drugs. www.aidsresearch.org

About the Clinical AIDS Research and Education Center (CARE Center)

The mission of the CARE Center is to facilitate a broad program of clinical, behavioral and prevention research in HIV, and to develop and clinically evaluate new treatment and novel therapeutic approaches for HIV, HIV-related diseases, and complications of therapy to improve the patients' quality of life. The Care Center is the UCLA base for the AIDS Prevention and treatment Clinical Trials Unit. For more information, visit http://www.uclacarecenter.org/

About The HIV Vaccine Trials Network (HVTN)

The HIV Vaccine Trials Network (HVTN) is an international collaboration of scientists and educators searching for an effective and safe HIV vaccine. HVTN's mission is to facilitate the process of testing preventive vaccines against HIV/AIDS. Our organization conducts all phases of clinical trials, from evaluating experimental vaccines for safety and the ability to stimulate immune responses, to testing vaccine efficacy. Support for HVTN comes from the National Institute of Allergy and Infectious Diseases (NIAID) of the U.S. National Institutes of Health (NIH). www.hvtn.org; www.hopetakesaction.org

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