April 7, 2016

Media Contacts:

HVTN: Jim Maynard
jmaynard@fredhutch.org
(206) 667-5295

HPTN: Eric Miller
emiller@fhi360.org
(919) 384-6465

HVTN and HPTN Announce Initiation of Antibody Mediated Prevention (AMP) Study

First Study to Evaluate Efficacy of Broadly Neutralizing Monoclonal Antibody in Reducing Acquisition of HIV-1 Infection Among At Risk Populations

SEATTLE, WA and DURHAM, NC – The HIV Vaccine Trials Network (HVTN) and the HIV Prevention Trials Network (HPTN) today announced the initiation of HVTN 704/HPTN 085, also known as Antibody Mediated Prevention (AMP) or the AMP Study, a Phase 2b clinical trial to evaluate the safety and efficacy of VRC01, a broadly neutralizing monoclonal antibody (bnAb). AMP is the first study to evaluate whether bnAbs are effective in reducing acquisition of HIV-1 infection among at-risk populations.

“Injections or infusions of antibodies to prevent acquisition of an infectious disease have been utilized in medicine for decades,” said Larry Corey, M.D., study chairperson for HVTN 704/HPTN 085 and principal investigator for the HVTN. “The remarkable advance in technologies to isolate and manufacture human monoclonal antibodies in concentrations high enough to potentially prevent HIV is a major advance and provides the underlying principle for our enthusiasm for these trials."

The clinical trial is a randomized, double-blind, placebo-controlled, multi-center, global effort conducted in the U.S., Brazil, and Peru and will enroll 2700 men or transgender persons (TG) who have sex with men or TG persons. Study participants will be randomized to receive VRC01 or placebo by intravenous (IV) infusion every eight weeks. Infusions will continue for 72 weeks for HIV-uninfected participants in all groups, with follow up for 20 additional weeks. A parallel study, HVTN 703/HPTN 081, will be initiated later this year in sub-Saharan Africa and will enroll 1500 sexually active women.

AMP is being sponsored and funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health. The NIAID Vaccine Research Center discovered the VRC01 antibody and manufactured it for this trial.

"This study represents an important next step in developing agents that can prevent HIV infection by using bnAbs," said Myron Cohen, M.D., study chairperson for HVTN 704/HPTN 085 and principal investigator for the HPTN. “AMP will leverage the research expertise, resources and reach of two NIAID-funded HIV prevention trial networks, and underscores our commitment to innovation and identification of new interventions to prevent HIV transmission."

"New HIV infections have continued to increase in our most vulnerable populations in the United States, including African American men who have sex with men," said Srilatha Edupuganti, M.D. M.P.H., co-chairperson of HVTN 704/HPTN 085 and associate professor of medicine, Emory University School of Medicine. "The use of bnAbs offers new hope to stem that tide as we have for other at-risk populations here and around the world."

About HVTN

The HIV Vaccine Trials Network (HVTN) is the largest worldwide clinical trials network dedicated to the development and testing of HIV/AIDS vaccines. The HVTN is an international collaboration that 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 the HVTN comes from the National Institute of Allergy and Infectious Diseases (NIAID), part of the U.S. National Institutes of Health (NIH). The Network’s HIV Vaccine Trial Units are located at leading research institutions in 27 cities on four continents. The Network’s headquarters are at the Fred Hutchinson Cancer Research Center in Seattle, Washington. For more information, visit www.hvtn.org.

About HPTN

The HIV Prevention Trials Network (HPTN) is a worldwide collaborative clinical trials network that brings together investigators, ethicists, community and other partners to develop and test the safety and efficacy of interventions designed to prevent the acquisition and transmission of HIV. HPTN studies evaluate new HIV prevention interventions and strategies in populations and geographical regions that bear a disproportionate burden of infection. The HPTN research agenda is focused primarily on the use of integrated strategies: use of antiretroviral drugs (antiretroviral therapy and pre-exposure prophylaxis); interventions for substance abuse, particularly injection drug use; behavioral risk reduction interventions and structural interventions. For more information, visit www.hptn.org.

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