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**Initiation of Antiretroviral Treatment
Protects Uninfected Sexual Partners from HIV Infection (HPTN Study 052)**

*96% reduction in HIV transmission, according to study conducted
by HIV Prevention Trials Network*

Washington, DC - Men and women infected with HIV reduced the risk of transmitting the virus to their sexual partners through initiation of oral antiretroviral therapy (ART), according to findings from a large multinational clinical study conducted by the HIV Prevention Trials Network (HPTN), a global partnership dedicated to reducing the transmission of HIV through cutting-edge biomedical, behavioral, and structural interventions.

The study, known as HPTN 052, was designed to evaluate whether immediate versus delayed use of ART by HIV-infected individuals would reduce transmission of HIV to their HIV-uninfected partners and potentially benefit the HIV-infected individual as well. Findings from the study were reviewed by an independent Data and Safety Monitoring Board (DSMB). The DSMB recommended that the results be released as soon as possible and that the findings be shared with study participants and investigators. The DSMB concluded that initiation of ART by HIV-infected individuals substantially protected their HIV-uninfected sexual partners from acquiring HIV infection, with a 96 percent reduction in risk of HIV transmission. HPTN 052 is the first randomized clinical trial to show that treating an HIV-infected individual with ART can reduce the risk of sexual transmission of HIV to an uninfected partner.

“This is excellent news,” said Dr. Myron Cohen, HPTN 052 Principal Investigator and Associate Vice Chancellor for Global Health and Director of the Institute of Global Health and Infectious Diseases at the University of North Carolina at Chapel Hill. “The study was designed to evaluate the benefit to the sexual partner as well as the benefit to the HIV-infected person. This is the first randomized clinical trial to definitively indicate that an HIV-infected individual can reduce sexual transmission of HIV to an uninfected partner by beginning antiretroviral therapy sooner. HPTN recognizes the significant contribution that this study’s participants have made to furthering the progress in HIV treatment and prevention. We are very grateful for their participation.”

HPTN 052 began in April 2005 and enrolled 1,763 HIV-serodiscordant couples (couples that have one member who is HIV-infected and the other who is HIV-uninfected), the vast majority of which (97 percent) were heterosexual. The study was conducted at 13 sites across Africa, Asia and the Americas. The HIV-infected person was required to have a CD4 cell count between 350-550 per cubic millimeter (cells/mm³) at enrollment, and therefore did not require HIV treatment for his or her own health. Couples were randomized to one of two groups. In one group, the HIV-infected person immediately began taking ART (immediate ART group). In the other group, the HIV-infected person began ART when his or her CD4 cell count fell below 250 cells/mm³ or if he/she developed an AIDS-related illness (the delayed ART group).

Throughout the study, both groups received HIV-related care that included counseling on safe sex practices, free condoms, treatment for sexually transmitted infections, regular HIV testing, and frequent evaluation and treatment for any complications related to HIV infection. Each group received the same amount of care and counseling. Any HIV-uninfected person who became HIV-infected during the course of the study was referred to local services for appropriate medical care and treatment.

“This rigorously conducted clinical trial demonstrates that ART dramatically reduces HIV transmission from an infected partner to an uninfected spouse or partner,” states Sten Vermund, HPTN Principal Investigator and Amos Christie Chair of Global Health at the Vanderbilt University School of Medicine. “Earlier therapy is a superior option that benefits both an infected individual and his or her uninfected partner and we support global efforts to offer ART to everyone who needs it.”

Among the 877 couples in the delayed ART group, 27 HIV transmissions occurred. This was in contrast to only one (1) transmission that occurred in the immediate ART group. This difference was highly statistically significant. The viruses transmitted in these 28 cases were confirmed to be linked by genetic analysis, confirming that the source of the new infection was the previously HIV-infected partner.

In the originally HIV-infected individuals themselves, 17 cases of extrapulmonary tuberculosis occurred in the delayed ART group, compared with three (3) cases in the immediate ART group, also a statistically significant finding. There were also 23 deaths during the study. Thirteen (13) occurred in the delayed ART group and 10 in the immediate ART group. Study participants and investigators are being informed of the results, and HIV-infected participants in the delayed ART group will be offered ART. All study participants will continue to be followed for at least one more year.

“Previous data about the potential value of antiretrovirals in making HIV-infected individuals less infectious to their sexual partners came largely from observational and epidemiological studies,” said NIAID Director Anthony S. Fauci, M.D. “This new finding convincingly demonstrates that treating the infected individual — and doing so sooner rather than later — can have a major impact on reducing HIV transmission.”

“The HPTN 052 study provides compelling evidence for a new HIV prevention approach that links prevention and care efforts,” said Quarraisha Abdool Karim, HPTN co-principal investigator and associate scientific director of CAPRISA. “Strategies for scaling up knowledge of HIV status and increasing treatment coverage are critical next steps to realizing the public health benefits of this finding. This is also very good news for women who bear a disproportionate burden of HIV infection acquired from infected male partners but have few options to reduce their risk especially if their partner refuses to use condoms consistently.”

Recently released data from another study, HPTN 043, demonstrated that community mobilization boosts HIV testing in developing countries and is one option for effectively increasing coverage of HIV testing services. The HPTN is evaluating a test, link to care, plus treat approach for prevention of HIV transmission in HPTN 065, a study currently underway in the USA. This study will demonstrate the population-level impact of increased knowledge of HIV status and linkage to care on HIV transmission.

About HPTN 052

HPTN 052 is a randomized, controlled trial designed to evaluate the effectiveness of antiretroviral therapy to prevent the sexual transmission of HIV in serodiscordant couples. The trial is conducted by the HIV Prevention Trials Network (HPTN) and funded by the National Institute for Allergy and Infectious Diseases (NIAID) at the US National Institutes of Health (NIH). Additional support was provided by the NIAID-funded Adult Clinical Trials Group. The antiretroviral drugs used in the study were made available by Abbott Laboratories; Boehringer Ingelheim Pharmaceuticals, Inc.; Bristol-Myers Squibb; Gilead Sciences; GlaxoSmithKline; and Merck & Co., Inc.

About HIV Prevention Trials Network (HPTN)

The HIV Prevention Trials Network (HPTN) is a partnership between scientists and communities around the world to develop, evaluate, and implement cutting-edge biomedical, behavioral, and structural interventions to reduce the transmission of HIV. HPTN uses randomized controlled clinical trials, designed and conducted according to the highest scientific and ethical standards, to identify the best combinations of interventions for the populations at highest risk of HIV infection worldwide. HPTN is largely funded by National Institute for Allergy and Infectious Diseases with additional funding from National Institute on Drug Abuse and National Institute for Mental Health, at the US National Institutes of Health.

For more information on HPTN, see www.hptn.org

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