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HIV Prevention Trial (HPTN 052) Releases New Findings

Early initiation of ART leads to 96% reduction in HIV transmission according to study conducted by HIV Prevention Trials Network

Rome, Italy – Detailed data from the landmark HIV Prevention Trials Network (HPTN) 052 study are being presented today at the 6th IAS Conference on HIV Pathogenesis, Treatment and Prevention (IAS 2011). The HPTN 052 study found that men and women, who were already infected with HIV, had a reduced risk of transmitting the virus to their uninfected sexual partners by 96% through early initiation of combination antiretroviral therapy (cART).

At today's presentation of the HPTN 052 results, original analyses are being presented for the first time. These new data of early initiation of cART among HIV-infected individuals indicate that the protective effect for their HIV-uninfected partners may be even stronger than initially reported. In addition, the HPTN, the World Health Organization (WHO), the National Institutes of Health (NIH) and the International AIDS Society (IAS) are holding a joint press conference today at IAS 2011. During the press conference, the WHO will introduce progress in developing guidance for couples where one partner is HIV-infected and the other is not (serodiscordant). According to the WHO, in African countries with the highest HIV rates, close to half of the HIV-infected adults in stable relationships have an HIV-uninfected partner. In addition, more than half of new adult infections occur within such couples.

"HPTN 052 is the first randomized clinical trial to indicate definitively that an HIV-infected individual can reduce sexual transmission of HIV to an uninfected partner by beginning antiretroviral therapy sooner," said Dr. Myron Cohen, HPTN 052 Protocol Chair 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. "We could not be more pleased that the WHO is considering these findings in its work on guidance for serodiscordant couples."

HPTN 052 was designed to evaluate whether early versus delayed use of cART by HIV-infected individuals would reduce transmission of HIV to their uninfected partners and benefit the HIV-infected individuals as well. The initial trial results will be published online today (18th July) in the New England Journal of Medicine.

During the course of the study, 39 participants who had been HIV-uninfected at the start of the study became infected with HIV. Of those, 29 were linked transmissions, where the virus from the originally-infected partner was confirmed by genetic analysis to be the source of infection in the newly infected sexual partner. Of these 29

linked infections, only one infection occurred in the early cART arm. Based on the latest analyses, this one transmission most likely occurred close to the time the couple enrolled in the study and before HIV viral replication could have been suppressed by cART in the infected participant.

The new analyses also provide more insight as to how early initiation of cART benefits the HIV-infected person. Individuals who were put on early cART maintained higher absolute CD4 counts than those in the delayed arm, who received treatment when their CD4 counts fell below 250 cells/mm³ or an AIDS-related event occurred. Early cART was also associated with a 41% reduction in HIV-related illnesses or death, a direct benefit for the HIV-infected partner. The reliable suppression of HIV among HIV-infected people in the early treatment arm suggests potential impact on adherence when the infected individual is informed that their cART may also benefit their partner.

"WHO welcomes the exciting results of the study," said Dr. Gottfried Hirnschall, Director of HIV/AIDS Department at the World Health Organization. "These findings will be reflected in guidelines for couples HIV testing and counseling and also to develop broader guidance on the strategic use of antiretrovirals for treatment and prevention of HIV."

Over the past year, WHO has been developing recommendations for couples HIV testing and counseling. More than half of all people living with HIV do not know their infection status, and therefore, may transmit HIV unknowingly. By partners testing together and mutually disclosing their test results, couples can learn about their options for HIV prevention and treatment.

"Documenting that the early use of cART for both prevention and treatment provides a test-of-concept for a topic of global policy relevance," said Sten Vermund, HPTN Principal Investigator and Amos Christie Chair of Global Health at the Vanderbilt University School of Medicine. "Among heterosexual serodiscordant couples, cART is indeed effective at preventing transmission. Combined with other new prevention technologies, this finding brings us one step closer to an evidence-based approach to ending the HIV epidemic."

About HPTN 052

HPTN 052 is a randomized, controlled clinical 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 (ACTG). 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 (NIAID) with additional funding from National Institute on Drug Abuse (NIDA) and National Institute for Mental Health (NIMH), at the US National Institutes of Health (NIH). For more information on HPTN, please see www.hptn.org