



Media inquiries: Eric Miller, +1.919.384.6465; emiller@fhi360.org

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HPTN 052 HIV Prevention Study Demonstrates Sustained Benefit of Early Antiretroviral Therapy

VANCOUVER, B.C. and DURHAM, N.C. – Antiretroviral therapy (ART) for HIV infection provides lasting protection against the sexual transmission of the virus from infected men and women to their HIV-uninfected sexual partners, investigators from the HIV Prevention Trials Network (HPTN) reported today at the 8th International AIDS Society (IAS) Conference on HIV Pathogenesis, Treatment and Prevention in Vancouver, Canada.

The study, known as HPTN 052, began in 2005 and enrolled 1,763 HIV sero-discordant couples – where one person is HIV-infected and the other is not – at 13 sites in nine countries. The majority of the couples were heterosexual (97%). HIV-infected partners were assigned to start ART at the beginning of the study, called the “early” arm, or later in the study, called the “delayed” arm. Those on the delayed arm started ART when their bodies’ immune systems were declining. HPTN 052 was funded primarily by The National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health.

“These findings demonstrate that antiretroviral therapy, when taken until viral suppression is achieved and sustained, is a highly effective, durable intervention for HIV prevention,” said Myron Cohen, M.D., director of the Institute for Global Health and Infectious Diseases at the University of North Carolina at Chapel Hill and principal investigator for HPTN 052. “The HPTN 052 trial was designed to address two questions: whether providing antiretroviral therapy to an HIV-infected person would prevent HIV transmission to a sexual partner, and whether earlier antiretroviral therapy offered long-lasting health benefits, and the answer to both is a resounding yes.”

In 2011, an interim review of the study data showed a 96% reduction of HIV transmission within the couples assigned to early ART, which was considered a major breakthrough finding. After the release of the results, all participants in the delayed ART arm were offered the opportunity to begin ART, and the study continued for four more years. By the end of the study, 1,171 couples remained in follow-up.

As reported today, the final results show a sustained 93% reduction of HIV transmission within couples when the HIV-infected partner was taking ART as prescribed and viral load was suppressed. Notably, there were only eight cases of HIV transmission within couples after the HIV-infected partner was given ART. However, four of these eight cases were diagnosed soon after ART initiation and transmission likely occurred before the HIV-infected partner was virally suppressed. The other four were diagnosed when the HIV-infected partner had detectable levels of virus in the blood despite being on ART (treatment failure). Treatment failure may have occurred because participants either did not take their antiretroviral drugs as prescribed or had

an HIV strain that resisted or acquired resistance to one or more of the drugs in their treatment regimen.

HPTN 052 investigators are also reporting findings at the IAS conference concerning the relationship between viral load, viral suppression, treatment failure and drug resistance. Investigators found that having a relatively high level of HIV in the blood at the start of treatment was associated with a longer time to viral suppression, which, in turn, was associated with both treatment failure and a shorter time to treatment failure. In addition, the investigators found, among the HPTN 052 participants who failed treatment, those who had a higher viral load when they joined the study were more likely to develop resistance to their antiretroviral drugs. More research is needed to understand this association, according to the investigators.

“These results have important implications for programs seeking to combine other HIV prevention measures with treatment as prevention,” Dr. Cohen said. “In the setting of such programs, special efforts should be made to minimize HIV transmission risk before viral suppression has been achieved, to maintain suppression on ART, and to identify and address ART failure.”

About HPTN Study 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 was 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 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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