HPTN 084 Study Demonstrates Superiority of CAB LA to Oral FTC/TDF for the Prevention of HIV

Both cabotegravir and oral FTC/TDF have high efficacy for PrEP among women in sub-Saharan Africa

DURHAM, N.C. – Researchers from the HIV Prevention Trials Network (HPTN) announced today data from the HPTN 084 clinical trial indicate that a pre-exposure prophylaxis (PrEP) regimen of long-acting cabotegravir (CAB LA) injections once every eight weeks was safe and superior to daily oral tenofovir/emtricitabine (FTC/TDF) for HIV prevention among cisgender women in sub-Saharan Africa. During a planned review of study data, an independent Data and Safety Monitoring Board (DSMB) recommended the study sponsor—the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health—stop the blinded phase of the trial and share the results. The study was originally designed to continue through 2022.

NIAID has accepted the DSMB's recommendations and is releasing the results in the interest of public health. The study investigators will provide more detailed information about the study findings, including more comprehensive data, as soon as is feasible. The HPTN 084 study is jointly-funded through a unique partnership between NIAID, the Bill & Melinda Gates Foundation, and ViiV Healthcare. Study drugs are provided by ViiV Healthcare and Gilead Sciences, Inc.

"The results from HPTN 084 are incredibly important for women in Africa where lowering HIV incidence remains a priority," said Dr. Sinead Delany-Moretlwe, HPTN 084 protocol chair, director of research at Wits Reproductive Health and HIV Institute, and research professor at the University of the Witwatersrand in Johannesburg, South Africa. "We know that adherence to a daily pill continues to be challenging, and an effective injectable product such as long-acting CAB is a very important additional HIV prevention option for them. We are grateful to the women who volunteered for this study and the research staff, as this study would not have been possible without their commitment to HIV prevention."

Overall, HPTN 084 enrolled 3,223 cisgender women at research sites in Botswana, Eswatini, Kenya, Malawi, South Africa, Uganda, and Zimbabwe. The average age of study participants was 26 years and 57% of participants were 18-25 years old. Eighty-two percent of the women enrolled were not living with a partner, 55% reported two or more partners in the past month, with 34% having a primary partner who is reported to be living with HIV or having an unknown HIV status. A total of 38 HIV infections occurred during follow-up, with four infections in the CAB LA arm (incidence rate 0.21%) and 34 infections in the FTC/TDF arm (incidence rate 1.79%). The hazard ratio in the CAB LA versus FTC/TDF arm was 0.11 (95% CI 0.04-0.32). Approximately nine times more incident HIV infections occurred in the FTC/TDF arm than in the CAB arm. These results meet the statistical criteria for superiority of CAB LA compared to FTC/TDF in the HPTN 084 study population. The higher-than-expected level of adherence to FTC/TDF throughout the study and overall low incidence rate in both arms of the study clearly demonstrate both drugs were highly effective at preventing HIV acquisition.

"After years of evaluating HIV prevention strategies for women, I am thrilled that we have found CAB LA so effectively reduces HIV acquisition and provides women more choices in how to protect themselves," said Dr. Mina Hosseinipour, HPTN 084 protocol co-chair, professor of medicine at the University of North Carolina (UNC) at Chapel Hill School of Medicine and scientific director of UNC Project-Malawi in Lilongwe, Malawi.

Earlier this year, the HPTN 083 clinical trial showed that a PrEP regimen containing CAB LA injected once every eight weeks was superior to daily oral FTC/TDF for HIV prevention among cisgender men and transgender women who have sex with men.

“The results from HPTN 084 along with the HPTN 083 results released earlier this year show how far we have come in the fight against HIV,” said Dr. Myron Cohen, HPTN co-principal investigator and director of the Institute for Global Health at the University of North Carolina in Chapel Hill. “A highly effective product like CAB LA that does not require a daily pill can be an important part of ending the epidemic globally.”

“The HPTN is thrilled by these outstanding results, a milestone for the prevention of HIV among women,” said Dr. Wafaa El-Sadr, HPTN co-principal investigator, director of ICAP and professor of epidemiology and medicine at Columbia University in New York. “These findings motivate continued evaluation of the safety of CAB LA in adolescents, a group at substantial risk for HIV infection. Defining the safety of CAB LA in adolescents will hopefully lead to faster access to CAB LA, once approved for use as PrEP.”

About HPTN

The HIV Prevention Trials Network (HPTN) is a worldwide collaborative clinical trials network that brings together investigators, ethicists, community members and other partners to develop and test the safety and efficacy of interventions designed to prevent the acquisition and transmission of HIV. NIAID, NIMH, Office of The Director, and NIDA, all part of NIH, co-fund the HPTN. The HPTN has collaborated with more than 85 clinical research sites in 19 countries to evaluate new HIV prevention interventions and strategies in populations that bear a disproportionate burden of infection. The HPTN research agenda – more than 50 trials ongoing or completed with over 161,000 participants enrolled and evaluated – 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 hptn.org.

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