BOTSWANA HARVARD AIDS INSTITUTE PARTNERSHIP FOR HIV RESEARCH AND EDUCATION

December 01, 2020

PRESS RELEASE

Long-Acting Injectable Cabotegravir Proves Superiority over Daily Oral Truvada for HIV Prevention in Women

The HIV Prevention Trials Network (HPTN) on the 9th of November 2020 announced results from HPTN 084 study, a global randomized, controlled, double-blind study that compared the safety and efficacy of long-acting injectable cabotegravir (CAB LA) to daily oral tenofovir/emtricitabine (FTC/TDF) (Truvada) for pre-exposure prophylaxis (PrEP) in Cisgender women in Sub Saharan Africa including Botswana. The results indicates that a PrEP regimen of CAB LA injections taken once every eight weeks was safe and superior to daily oral FTC/TDF for HIV prevention among cisgender women.

The study enrolled 3,223 cisgender women in 20 research sites across 7 countries being 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 (82%) 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.

The trial recorded a total of 38 HIV infections that 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. The results meet the statistical criteria for superiority of CAB LA compared to FTC/TDF in the HPTN 084 study population. The adherence level to FTC/TDC was higher than expected throughout the study and there was overall low incidence rate in both arms of the study which demonstrate that both FTC/TDF and CAB LA proved highly effective for HIV prevention.

These results were released after a planned interim review of the study data by an independent Data and Safety Monitoring Board (DSMB) which recommended that the study results be announced and that the blinded placebo-controlled phase of the trial be stopped. During the blinded phase, neither the participants nor the investigators knew who was randomized to receive which medication. As the unbinding takes place,

Private Bag BO 320
Gaborone, Botswana
Phone: +267 267 3902671
Fax: +267 3901284
Website: wwww.bhp.org.bw

study participants will be told which drug they have been taking and offered an opportunity to switch from either FTC/TDF or CAB LA according to their preference.

Earlier this year, the HPTN 083 clinical trial which compared the safety and efficacy CAB LA to daily oral (FTC/TDF) for pre-exposure prophylaxis (PrEP) in Cisgender men and transgender women who have sex with men showed that a PrEP regimen containing CAB LA injected once every eight weeks was superior to daily oral FTC/TDF for HIV prevention. Overall, results from both the HPTN 084 and HPTN 083 indicate that CAB LA is superior to daily oral FCT/TDF and is highly effective for the prevention of HIV acquisition in both cisgender men and women.

"We are pleased by this positive outcome of a demonstration that CAB LA is safe and highly effective for HIV prevention and we would like to thank our study participants for contributing to the ever growing body of science. It is very heartwarming that the drug is safe, well tolerated and highly effective in both men and women. While the CAB LA is superior and will surely enhance adherence, it is pleasing that both CAB LA and Oral FTC/TDF are safe and have high efficacy which gives the people an alternative to choose which drug they prefer," said Dr Moeketsi Joseph Makhema, the Chief Executive Officer (CEO) of the Botswana Harvard AIDS Institute Partnership (BHP).

As we commemorate the 32nd World Aids Day whose theme is "Ending the HIV/AIDS Epidemic: Resilience and Impact" the Botswana Harvard Aids Institute joins the world in a clarion call towards commitment to end the HIV/AIDS epidemic.

The demonstrated efficacy of multiple strategies in the HIV/AIDS treatment, care and prevention tool box provides robust interventions which if employed in concert have the capacity to end the HIV/AIDS epidemic.

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 and NIDA 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.

About BHP

Private Bag BO 320
Gaborone, Botswana
Phone: +267 267 3902671
Fax: +267 3901284
Website: wwww.bhp.org.bw

Established in 1996, the Botswana Harvard AIDS Institute Partnership (BHP) is a world renowned public health institute established through a partnership between the Government of Botswana represented by the Ministry of Health and Wellness (MOHW) and Harvard University in US represented by the Harvard T.H.Chan School of Public Health (HSPH). As a world-class research center, BHP is the leading HIV/AIDS research in Botswana and its mission is to fight HIV/AIDS and emerging health challenges through innovative research, education and capacity building that impacts policy and practice. Areas of research include clinical and basic science; epidemiology, socio-behavioral science and community based bio-clinical research relevant to the AIDS epidemic and other emerging public health challenges.

For more information, contact:

Dr Alice Sehurutshi
HPTN Study Physician
Botswana Harvard AIDS Institute Partnership
Private Bag BO320, Gaborone
Tel: 3922540
Email: asehurutshi@bhp.org.bw

Dr Moeketsi Joseph Makhema
Chief Executive Officer
Botswana Harvard AIDS Institute Partnership
Private Bag BO320, Gaborone
Tel: 3902671, Fax: 3901284
Email: jmakhema@bhp.org.bw