HPTN HIV Prevention Trials Network

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# HIV Prevention Trials Network (HPTN) Announces Initiation of HPTN 084

## *First Large-Scale Study in Women of a Long-Acting Injectable to Prevent HIV*

**DURHAM, N.C.** – The HIV Prevention Trials Network (HPTN) today announced the initiation of HPTN 084, a Phase 3 double-blind safety and efficacy study of long-acting injectable cabotegravir (CAB) compared to a combination of daily oral tenofovir disoproxil fumarate 300 mg plus emtricitabine 200 mg (TDF/FTC). The study is the first large-scale clinical trial of a long-acting injectable medication for HIV prevention in sexually active women. If found to be safe and effective for HIV pre-exposure prophylaxis (PrEP), injectable CAB may be an easier, more desirable, discreet alternative to daily oral TDF/FTC for some women. Several countries have approved TDF/FTC for PrEP including Australia, Canada, France, Kenya, Peru, South Africa, and the U.S.

"The development of safe alternative options for PrEP could increase HIV prevention choices for women," said Sinead Delany-Moretlwe, MBBCh, Ph.D., DTM&H, HPTN 084 protocol chair and research director at RHI, University of the Witwatersrand in Johannesburg, South Africa. "Long-acting injectable agents like cabotegravir may be more acceptable to some women for HIV prevention by providing an alternative with different adherence requirements."

HPTN 084 will enroll approximately 3,200 HIV-uninfected, sexually active women in Botswana, Kenya, Malawi, Swaziland, South Africa, Uganda, and Zimbabwe. Study participants will be assigned by chance to either CAB or TDF/FTC in a double-blind manner, meaning neither the participant nor research staff know what the participant is receiving. Study participants will be transitioned to locally available HIV prevention services when their participation in the study ends.

"In sub-Saharan Africa, more than 60 percent of all people living with HIV are women," said Wafaa El-Sadr M.D., M.P.H., HPTN co-principal investigator and professor of epidemiology and medicine at Columbia University. "Young African women share a disproportionate burden and are especially vulnerable to this epidemic."

A related study, HPTN 083, is testing the safety and efficacy of injectable CAB for HIV prevention in 4,500 men who have sex with men and transgender women who have sex with men in seven countries in the Americas, Asia and Africa.

"If cabotegravir is shown to protect against HIV acquisition, the long-acting injectable agent could become another major tool in our HIV prevention toolbox," said Myron Cohen, M.D., HPTN co-principal investigator and director of the Institute for Global Health and Infectious Diseases at the University of North Carolina at Chapel Hill.

HPTN 084 is jointly funded through a unique partnership of the U.S. National Institute of Allergy and Infectious Diseases, part of the U.S. National Institutes of Health; the Bill & Melinda Gates Foundation; and ViiV Healthcare. Study drugs are provided by ViiV Healthcare and Gilead Sciences, Inc.

For more information about HPTN 084, visit hptn.org, or ClinicalTrials.gov using study identifier NCT03164564.

**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. NIH funds HPTN. For more information, visit www.hptn.org.

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