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Two studies to test safety of injectable drugs to prevent HIV

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The HIV Prevention Trials Network (HPTN) has launched two new phase 2 studies, HPTN 076 and HPTN 077, which are designed to evaluate new drugs to protect people from getting infected with HIV.

HPTN 076 and HPTN 077 are among the first studies to test long-acting, injectable antiretroviral drugs in persons without HIV infection. Antiretroviral drugs are commonly used now as treatment in individuals with HIV infection.

The studies are funded by the National Institute of Allergy and Infectious Diseases, which is part of the U.S. National Institutes of Health.

Both studies evaluate the safety and acceptability of long-acting injectable drugs, for eventual use for pre-exposure prophylaxis, or PrEP. At the present time, the combination pill including emtricitabine and tenofovir (Truvada) has been approved by the U.S. Food and Drug Administration (FDA) for use as daily oral PrEP for the prevention of HIV infection. However, taking a daily pill has been shown in some PrEP studies to be problematic. Having an option of a drug that is injected and can stay in the body for several months to protect against HIV infection could be a major advance for those at risk, and offer an important addition to the portfolio of HIV prevention options.

"In the absence of an effective vaccine, the start of these studies marks an important step in our quest to find the best HIV prevention strategies

that have the potential to bring the HIV epidemic to a halt," said Myron Cohen, HPTN Principal Investigator. "If proven to be a safe and viable option for our study participants, these HPTN clinical trials could inform the future of HIV prevention."

HPTN 076 is testing the safety and acceptability of TMC278 LA, which is the long-acting form of rilpivirine, a non-nucleoside reverse transcriptase inhibitor. Women without HIV infection who are at low risk for getting infected are being enrolled in this study in South Africa, United States, and Zimbabwe. The pill form of rilpivirine is approved by the FDA for use as HIV treatment. The women will receive six sets of injections over a 10-month period and will be followed for eight months. HPTN 076 is being conducted in collaboration with PATH and Janssen Sciences Ireland UC.

HPTN 077 is testing the safety, tolerability, and acceptability of the long-acting form of the oral drug GSK1265744, or cabotegravir, which is an integrase inhibitor, in both men and women. Cabotegravir is being simultaneously developed for HIV treatment and prevention, and is not yet approved by the FDA. The study is enrolling both men and women without HIV infection at low risk for getting HIV at sites in Brazil, United States Malawi, and South Africa. Study participants will receive three sets of injections over six months, and will be followed for a year after their last injection. This study is a collaboration with GlaxoSmithKline and ViiV Healthcare.

"The HPTN is eager to assess these promising drugs for PrEP in diverse populations and diverse settings—men, women and in the U.S. as well as other countries around the world," said Wafaa El-Sadr, HPTN Principal Investigator. "These two studies are an important step forward to advancing the PrEP Scientific Agenda."

More information: www.hptn.org/research_studies/hptn076.asp

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Provided by HIV Prevention Trials Network