PRESS STATEMENT

UNAIDS welcomes new tool for HIV prevention for gay men and other men who have sex with men and transgender women

Ground-breaking new study shows the efficacy of a long-acting injectable to prevent HIV

GENEVA, 19 May 2020—UNAIDS warmly welcomes the announcement that the long-acting injectable cabotegravir is safe and effective in preventing HIV among gay men and other men who have sex with men and transgender women. The HIV Prevention Trials Network (HPTN) 083 study enrolled almost 4600 HIV-negative people from across more than 40 sites in North and South America, Asia and Africa.

“This is a breakthrough that will have a significant impact on the lives of gay men and other men who have sex with men and transgender women when they are at higher risk of HIV infection.” said Shannon Hader, UNAIDS Deputy Executive Director, Programme. “We are particularly pleased that the study met its targets to recruit substantial numbers of younger black men who have sex with men and transgender women, the very people for whom accessing effective HIV prevention still remains a huge challenge.”

In 2018, UNAIDS estimates that there were 1.7 million new HIV infections, 54% of which were among key populations and their partners, including gay men and other men who have sex with men, transgender women, sex workers, people who inject drugs, people in prison, clients of sex workers and sex partners of other key populations.

Pre-exposure prophylaxis (PrEP)—HIV-negative people using antiretroviral medicine to prevent HIV infection—is an important element in the HIV combination prevention toolkit. PrEP allows people to reduce their risk of becoming infected with HIV, particularly during periods of increased risk in their lives. It may also provide reassurance and reduce anxieties when the risks are uncertain.

Once it has passed regulatory approval, and when production of affordable cabotegravir can be scaled up, gay men and other men who have sex with men will have the choice of three highly effective ways to use PrEP to prevent HIV infection: daily pills, pills taken before and after sexual activity (event-driven PrEP) or an injection every two months. Transgender women will be able to choose between injections or daily pills, since the World Health Organization does not recommend event-driven PrEP because of possible drug interactions with some hormones. Injections of cabotegravir every two months are an important option for people who find it hard to take a pill every day, yet remain vulnerable to HIV infection.

The trial was scheduled to continue for at least another year, but the first interim analysis of the data was brought forward a few weeks because of the potential disruption that the COVID-19

pandemic might cause to high-quality clinical trial procedures. The Data and Safety Monitoring Board (DSMB) in the United States of America reviewed the data up to March 2020 and found that there was already clear evidence that cabotegravir was highly effective and not inferior to the currently recommended oral PrEP regimen.

Half of the study group were given oral PrEP and were injected with a placebo; the other half were given a cabotegravir injection and took a placebo pill. The study found a total of 12 HIV infections in the group using the injectable compared to 38 in the group taking the daily pill. The side-effects of both treatments were relatively mild, with only 2.2% of people in the injection group choosing to stop having the injections because of painful reactions. The DSMB therefore recommended that the study be halted and that all participants be notified of the result. The participants will be able to choose which regimen they wish to continue on.

Despite good adherence in the oral group and very few discontinuations in the injection group, the overall incidence of HIV infection in the study was 0.79 per 100 person-years. Planned analyses will explore why those 50 infections occurred among the 4565 trial participants.

An additional study (HPTN 084) is ongoing to establish the efficacy of the long-lasting injectable in non-transgender women. To date, more than 3000 sexually active women in seven African countries have enrolled in the study. Those results are expected in November.

“We are eagerly awaiting the results of the ongoing HPTN 084 study among African women,” said Dr Hader. “We hope that by the end of this year there will be equally good news for women around the world.”

HTPN 083 was conducted by the HPTN and funded by ViiV Healthcare and the United States National Institute of Allergy and Infectious Diseases. Cabotegravir has not yet been approved for the treatment or prevention of HIV as a single agent by regulatory authorities anywhere in the world. ViiV Healthcare plans to use the data from HPTN 083 for future regulatory submissions.

UNAIDS congratulates the research teams and urges continued investment in research and development for HIV vaccines, diagnostics, preventative medicines, treatment and a cure.

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