

## PRESS STATEMENT

### **UNAIDS and WHO welcome new findings that could provide an additional tool for HIV prevention for men who have sex with men**

**GENEVA, 23 November 2010**—The Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organization (WHO) welcome new research published today showing that an antiretroviral drug combination, taken daily as a prophylaxis, in conjunction with use of condoms, reduces the risk of HIV infection by an average of 43.8% for HIV-negative men and transgender women who have sex with men.

UNAIDS and WHO congratulate the iPrEx study team for the exemplary conduct of this complex multi-site, multi-language trial.

Men who have sex with men are often marginalized, hard to reach, and have poor access to HIV prevention services. New data from 43 countries show that slightly more than half of such men benefit from HIV prevention programmes. In addition, nearly 80 countries criminalize same-sex relations.

“This positive result is going to give hope to millions of men who have sex with men and help them protect themselves and their loved ones,” said Michel Sidibé, UNAIDS Executive Director. “This new tool can be a valuable addition to current HIV prevention approaches and help bring about a prevention revolution.”

The iPrEx study enrolled 2499 men in six countries, primarily in South America. Volunteers who took a daily dose of tenofovir/emtricitabine (TDF/ FTC) as oral pre-exposure prophylaxis (PrEP) were less likely to become infected with HIV than those who took the placebo. Those who took the pill consistently had higher effectiveness in preventing HIV infection.

“The trial opens exciting new prospects. It shows that oral pre-exposure prophylaxis can reduce the risk of HIV infection in men who have sex with men. We look forward to further examining these data to consider how we can best use this tool to enhance HIV prevention when used in combination with other prevention such as condom promotion in this population at higher risk,” said Dr Margaret Chan, WHO Director-General.

The results from the study constitute proof of concept of the safety and partial effectiveness of oral PrEP. This study also showed the potential effects of combination prevention approaches—combining consistent condom use, frequent HIV testing, counselling, and treatment of sexually transmitted infections with pre-exposure prophylaxis for maximum prevention gains.

The announcement today complements results from the CAPRISA trial released earlier this year. That study found a vaginal microbicide gel containing tenofovir used before and after sex to be 39% effective in preventing new HIV infections in women.

The iPrEx trial is part of efforts to develop new HIV prevention options for people at risk of HIV exposure. In addition, on-going studies testing the use of similar drugs to prevent HIV

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infection will provide more safety and effectiveness data from diverse populations including heterosexual women, serodiscordant couples, and people who inject drugs.

UNAIDS and WHO strongly advocate combination prevention as the most effective strategy to reduce HIV transmission. This includes correct and consistent use of male and female condoms, delaying sexual debut, having fewer partners, avoiding penetrative sex, male circumcision, reducing stigma and discrimination, and the removal of punitive laws. The male latex condom is the single, most efficient, available technology to reduce the sexual transmission of HIV and other sexually transmitted infections. The iPrEx study findings provide hope that men who have sex with men may have an additional means to protect themselves against HIV in addition to condoms.

UNAIDS and WHO will work with the study team and convene experts and key stakeholders to assess implications of these results for potential safe and effective delivery of PrEP as an additional HIV prevention tool for men who have sex with men. Close clinical evaluation, regular HIV testing, counselling to support pill-taking behaviour and safer sex, and safety monitoring are likely to be key components of effective PrEP programming.

The trial team at each study site will now provide access to the drug combination to all study participants, including those in the placebo group. This is in line with published good participatory practice guidelines and ethical standards for biomedical HIV prevention trials. UNAIDS and WHO welcome the efforts of the study teams to gather information on what implementation strategies for safe and appropriate PrEP work best.

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