

## TRIALS OF TENOFOVIR-BASED PREVENTION METHODS: AT A GLANCE

### DAILY ORAL TENOFOVIR-BASED PREP

#### Four trials found protection with oral PrEP

- The **Partners PrEP** trial studied daily PrEP using TDF/FTC or TDF in HIV-negative women and men aged 18 to 65 with HIV-positive partners or spouses (serodiscordant couples) in East Africa. The trial found high rates of adherence at 81 percent for TDF/FTC and 83 percent for TDF. Protection in Partners PrEP was also high at 75 percent [CI\*=55–87] for TDF/FTC and 67 percent [CI=44–81 percent] for TDF for both HIV-negative women and men. The US CDC-sponsored **TDF2 trial** in Botswana also found that daily oral TDF/FTC reduced risk of HIV infection by 62 percent [CI=22–83] in female and male participants. The **iPrEx** study tested daily oral TDF/FTC in MSM and found 42 percent risk reduction [CI=18-60]. The **Bangkok Tenofovir Study** tested daily oral tenofovir in men and women who inject drugs and found a 49 percent risk reduction [CI=9.6-72.2].

#### Two trials found no protection with oral PrEP in women

- The **FEM-PrEP** trial found no effect with daily oral TDF/FTC among a group of African women aged 18 to 35 from Kenya, South Africa and Tanzania, who were at risk of HIV through sexual transmission. Analyses from the FEM-PrEP trial reported that less than half of the women in the trials had any drug detected in their blood. Adherence was too low for the trial to determine whether the intervention provided any protection.
- The majority of participants in the **VOICE** trial were single, young women aged 18 to 45. The trial took place in South Africa, Uganda and Zimbabwe. VOICE participants were similar in age and relationship status to the women enrolled in FEM-PrEP. Like FEM-PrEP, VOICE found that none of the interventions tested—daily oral TDF, daily oral TDF/FTC and daily 1% tenofovir gel—reduced the risk of HIV infection. In the VOICE trial, an analysis of blood samples from a subset of participants showed that drug was detected in less than 30 percent of women in all product groups. Analysis of adherence in the VOICE trial is ongoing and includes examination of drug levels in vaginal fluid samples and two qualitative behavioral studies.

### TENOFOVIR GEL

#### One trial to date has shown evidence that a microbicide—1% tenofovir gel—reduces HIV risk in women

- The **CAPRISA 004** trial in 889 South African women found that 1% tenofovir gel reduced women's risk of HIV infection via vaginal sex by 39 percent overall. Women in the trial were counseled to use the gel within 12 hours before and after sex, a regimen known as BAT-24. There is an ongoing open-label study (where all participants are offered the product being tested and there is no placebo) of 1% tenofovir gel, called CAPRISA 008. This study will look at effective ways to deliver the gel in communities where the CAPRISA 004 trial took place.

#### One trial to date has shown that 1% tenofovir gel does not reduce HIV risk in women

- The **VOICE** trial, which was designed to test both oral (pill form) and topical (gel form) ARV-based prevention, found that 1% tenofovir did not reduce risk in women counseled to use it on a daily basis. The tenofovir gel arm was stopped early, after an interim DSMB review in 2011 found it to be safe but not effective in the study population.

#### One trial of 1% tenofovir gel is ongoing in women

- **FACTS 001** is a large-scale trial of tenofovir gel in South African women, which began enrolling in October 2011. The trial is testing the same BAT-24 dosing strategy evaluated in CAPRISA 004. FACTS 001 results are expected in late 2014.

#### One trial of a rectal formulation of 1% tenofovir gel is underway

- **MTN-017** is the first-ever Phase II trial of a rectal microbicide candidate, a rectal formulation of 1% tenofovir. It will enroll nearly 200 MSM at sites in Peru, South Africa, Thailand and the United States.

\* CI stands for Confidence Interval, a statistical measure of the reliability of a finding, which is given as a point estimate, such as a 35 percent reduction in risk of infection. The narrower the confidence interval around the point estimate, the more likely it is that the result is accurate.