March 4, 2013—The Microbicides Trial Network (MTN) announced results of its VOICE study today at the 20th Conference on Retroviruses and Opportunistic Infections (CROI). VOICE—Vaginal and Oral Interventions to Control the Epidemic—was designed to test whether antiretroviral (ARV) medicines commonly used to treat people with HIV are safe and effective in preventing sexual transmission of HIV in women as pre-exposure prophylaxis (PrEP).

The study was a phase IIB, double blind, placebo-controlled, five arm study evaluating daily dosing of oral tenofovir disoproxil fumarate (TDF) alone, and daily dosing of combination of oral TDF and emtricitabine (known as Truvada®) compared to oral placebo; and daily use of tenofovir gel (TFV) compared to the placebo gel. The VOICE study began in September 2009 and enrolled 5,029 women in Uganda, South Africa and Zimbabwe. Results released today show that of the three products tested in the VOICE study none proved to be effective because most participants did not use them daily as recommended. Drug was detected in less than a third of blood samples from women who were assigned the oral tablets and in less than a quarter of samples from women assigned to use the gel.

“We applaud MTN, and their participating sites, investigators and study participants for their enormous effort in undertaking this critically important study,” said Dr. Wafaa El-Sadr, HPTN Principal Investigator. “These findings underscore the need for continued research to understand risk perception and adherence facilitators/impediments, to enhance adherence with drugs used for prevention as well as to find alternate efficacious PrEP agents.”

These findings follow several PrEP studies in the past two years with seemingly inconsistent results. Partners PrEP, and TDF2 studies provided evidence that HIV acquisition among heterosexuals can be prevented by taking oral, daily ARV drugs, and the iPrEx study demonstrated efficacy among men who have sex with men (MSM). However, the FEM-PrEP and VOICE studies were unable to demonstrate efficacy.

“We must continue to expand our HIV prevention toolkit,” said HPTN Principal Investigator Mike Cohen. “While there have been mixed PrEP results in recent studies, this should not dissuade us from continuing to identify effective strategies to reduce HIV transmission in populations at risk around the world.”