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## **FACT SHEET**

### **HPTN 035 AT A GLANCE**

#### **Study Overview**

- HPTN 035 was a Phase II/IIb trial that evaluated the safety and effectiveness of the vaginal microbicides PRO 2000 (0.5 percent dose) and BufferGel for preventing male-to-female sexual transmission of HIV.
- The study was not designed to compare the two gels, but rather to compare each against a placebo gel with no active ingredient, and with no gel at all.
- The study was conducted between February 2005 and September 2008 among 3,099 HIV-negative women at seven clinical research sites in Malawi, South Africa, Zambia, Zimbabwe and the United States. Results were announced February 2009 at the Conference on Retroviruses and Opportunistic Infections (CROI) in Montreal.
- Women were randomized approximately in equal number to one of four study groups: BufferGel, PRO 2000 gel, placebo gel (with no active ingredient), or no gel. Participants assigned to the three gel groups were instructed to apply gel up to one hour before sexual intercourse using pre-filled applicators.

#### **Milestones**

- HPTN 035 provided the first indication from a clinical trial that a vaginal gel may prevent HIV infection.
- HPTN 035 was the first study of two microbicide gels, each with a different mechanism.
- HPTN 035 was the first study involving two control groups; one in which women used a placebo gel and one in which women used no gel.

#### **Results**

- PRO 2000 Gel was found to be 30 percent effective in preventing HIV infection. While encouraging, this level did not meet statistical relevance. Additional evidence is needed to conclusively determine whether PRO 2000 is an effective microbicide.
- BufferGel was found to have no effect on preventing HIV infection. About the same number of HIV infections occurred among women who used BufferGel, women who used placebo gel, and women who used no gel.
- Among the 3,099 women who took part in the study, 194 HIV infections occurred:
  - 36 infections occurred among women using PRO 2000 Gel
  - 54 infections occurred among women using BufferGel
  - 51 infections occurred among women using placebo gel
  - 53 infections occurred among women using no gel
- Both gels were found to be safe. Women who used BufferGel and PRO 2000 Gel had similar exam findings, laboratory test results, and other health outcomes compared to women who used placebo gel and women who used no gel.

**- more -**

- Women in the three gel groups reported using gel 81 percent of the time during sex and reported using condoms 72 percent of the time. Women who were in the no-gel group reported using condoms 81 percent of the time, a difference that is statistically different.
- Both BufferGel and PRO 2000 Gel were found to be acceptable. Nearly all women (99 percent) reported they would use the gels if approved for HIV prevention.

### **Additional Background**

- The study was conducted by the Microbicide Trials Network (MTN), an HIV/AIDS clinical trials network established and funded in 2006 by the National Institute of Allergy and Infectious Diseases (NIAID), with co-funding by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) and the National Institute of Mental Health (NIMH), all components of the U.S. National Institutes of Health (NIH). Prior to 2006, the study was conducted by the NIAID-funded HIV Prevention Trials Network (HPTN), from which the study gets its name.
- Salim S. Abdool Karim, MBChB, Ph.D., from the University of KwaZulu-Natal in Durban, South Africa, led the study as protocol chair.
- The clinical trial sites were:
  - Blantyre, Malawi - Malawi College of Medicine – Johns Hopkins University Clinical Research Site (Queen Elizabeth Central Hospital)
  - Lilongwe, Malawi - University of North Carolina Lilongwe Clinical Research Site (Kamuzu Central Hospital)
  - Durban, South Africa - Chatsworth Clinical Research Site (R.K Khan Hospital) of the South African Medical Research Council (MRC)
  - Hlabisa, South Africa - Hlabisa Clinical Research Site of the MRC
  - Lusaka, Zambia - Kamwala Health Centre Clinical Research Site of the Centre for Infectious Disease Research in Zambia
  - Harare, Zimbabwe - University of Zimbabwe-UCSF Collaborative Research Programme Clinical Research Sites at Spilhaus and Seke South Clinics
  - Philadelphia, Pa., USA - University of Pennsylvania
- HPTN 035 was funded by NIAID. Indevus Pharmaceuticals, Inc., of Lexington, Mass., USA, provided PRO 2000 and ReProtect, Inc., of Baltimore, Md., provided BufferGel. The U.S. Agency for International Development (USAID) provided funding to manufacture BufferGel for the study. Indevus has since been acquired by Endo Pharmaceuticals, Inc., of Chadds Ford, Pennsylvania.
- The UK Microbicides Development Programme is conducting another study of PRO 2000 gel which is expected to report results in November of this year. Known as MDP 301, the study is a Phase III trial of 9,404 women in South Africa, Tanzania, Uganda, and Zambia.

### **Why this Study is Important**

- Women account for half of the 33 million people living with HIV/AIDS worldwide. In sub-Saharan Africa, women account for 60 percent of all infected adults. In several southern African countries, young women aged 15 to 24 are at least three times more likely than their male peers to be infected with HIV.
- Among women, heterosexual intercourse remains the primary risk factor for HIV infection, and in many parts of the world, heterosexual intercourse is the driving force of the epidemic. Women are twice as likely as their male partners to acquire HIV during sex, due in part to biological factors that make women more vulnerable.

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More information is available at <http://www.mtnstopshiv.org/news/studies/hptn035>

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