Investigational Gel, Condom Reduce HIV Spread

BY ROBERT FINN

San Francisco — When used intravaginally in combination with a condom, the investigational microbicide PRO 2000/5 gel reduced HIV transmission by 30% in a large, international, randomized clinical trial. The finding, which fell short of statistical significance, was seen in a study called HPTN 035 (Phase II/IB Safety and Effectiveness Study of the Vaginal Microbicides BufferGel and 0.5% PRO 2000/5 Gel [P] for the Prevention of HIV Infection in Women). A reduction of 33% would have reached statistical significance according to the predetermined statistical approach. Jr. president of research at Family Health International, which designed and launched the trial. FHI is a nonprofit foundation in Research Triangle Park, N.C.

The study followed 3,899 women at one U.S. site and at sites in five African countries. All women were given free condoms, HIV risk reduction counseling, and diagnosis and treatment of sexually transmitted infections (STIs) at participating clinics. The study participants were then randomized to one of four groups. One-quarter were given PRO 2000/5 gel, one-quarter were given another microbicide called BufferGel, one-quarter were given a placebo gel, and the remaining women did not receive any gel. The gels were provided as single-use, prefilled applicators and the study particip- ants were instructed to apply one dose of the contents intravaginally up to 60 minutes before intercourse. The women were followed for an average of 20 months and were evaluated monthly; 94% of the women completed study visits through the 24-month period.

Participants in the three gel groups reported using the gel during 81% of all sex acts, and nearly all women (99%) said they would use the products if approved for free HIV prevention. Women in the three gel groups reported using condoms 72% of the time, and women in the no-gel group reported using condoms 81% of the time.

In all, 194 of the women acquired HIV; 36 women in the PRO 2000/5 group, 54 in the BufferGel group, 51 in the placebo gel group, and 51 among participants who used no gel. This corre- sponded to an effective rate of 38% for PRO 2000/5; a rate of 33% would have been statistically significant. In a sub- analysis based on reliability of condom use, there was little difference in the infection rate among women who used condoms more than 85% of the time. However, the infection rate was 4.6 per 100 person-years among the low-condom-use group for those who used PRO 2000/5 gel compared to 1.0 per 100 person-years among the low-condom-use women given PRO 2000/5 gel. The variation corresponded to an effectiveness rate of 78% for PRO 2000/5 gel.

Dr. Cates said that a separate trial of PRO 2000/5 gel, involving about 9,000 women, is expected to be completed by the end of 2009, with data available early in 2010. The investigational microbicide PRO 2000/5 gel (0.5% dose) was developed by Indevus Pharmaceuticals Inc. of Lexington, Mass., and is an entry/fusion inhi- bent designed to make it difficult for HIV to attach to and infect healthy cells. The investigational microbicide BufferGel was developed by ReProtect Inc. of Baltimore and is thought to work by boosting the natural acidity of the vaginal in the presence of seminal fluid.

The study was funded by the Nation- al Institute of Allergy and Infectious Diseases (NCT00714425). Indevus and ReProtect provided the microbicide, and the U.S. Agency for International Development provided funding to manufac- ture BufferGel for the study. Dr. Cates disclosed that he had no conflicts of interest.

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