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**New PRO2000 HIV-Prevention Findings Important Milestone on Path
Toward Development of Effective Vaginal Microbicide**

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Dr. Zeda Rosenberg, CEO of the International Partnership for Microbicides, issued the following statement on the results of the Phase II/IIb safety and effectiveness study of BufferGel and PRO2000 (0.5 percent concentration):

(Feb. 9, 2009) – The Microbicide Trials Network, a worldwide collaborative group funded by the US National Institutes of Health, has released final results from its Phase II/IIb safety and effectiveness study of two microbicides, BufferGel and PRO2000 (0.5 percent concentration), both vaginal gels being tested to prevent HIV transmission to women during sex. BufferGel's primary action is to lower vaginal pH while PRO2000 is a large charged polymer designed to interfere with HIV's interactions with its target cells.

Results from the four-year trial (HPTN 035), conducted in Malawi, South Africa, the United States, Zambia and Zimbabwe, show that both products are safe as tested. Quite importantly, while BufferGel unfortunately did not show a protective effect against HIV, the trial indicated that PRO2000 was at least 30% more effective than any other arm in the study in preventing HIV. Neither BufferGel nor PRO2000 showed protection against any other sexually transmitted infection.

After disappointing results from several previous microbicide trials, these findings will be heartening to every woman who has ever felt powerless in the face of HIV. These findings are also an important milestone because they confirm the fundamental premise of vaginal microbicide science: that a woman can use a product topically and stop HIV infection.

This trial was not designed to generate definitive data on this product at this efficacy level. While the 30% effect within this trial is not statistically significant, the data is highly supportive. Additionally, the protective effect of PRO2000 is corroborated by analysis of various subgroups of women within the study.

To bolster these results additional trials must be run to generate confirming data. Fortunately, another study of PRO2000 (0.5 percent concentration) by the UK-based Microbicides Development Programme (MDP), a partnership of African and European researchers, is ongoing with results expected by the end of this year. The MDP study is taking place in South Africa, Tanzania, Uganda and Zambia.

Some important secondary data emerged from the HPTN 035 study. The study showed that HIV infection rates were the same in the placebo control arm and in the no gel arm, suggesting that women did not change their HIV risk behaviour when using a gel product, an important result that helps validate the safe introduction of microbicides into communities.

This trial and the others that have gone before it strengthen our resolve to continue with the important research needed to address the global AIDS epidemic. While IPM was not involved in the trial of PRO2000 and BufferGel, we strongly applaud and acknowledge with great respect the trial sponsors, researchers, staff and more than 3,000 study participants for their hard work, skill and commitment to improve women's health around the world.

This and other studies of early microbicide candidates in recent years have underscored the challenges we face in HIV prevention research and microbicide development. But they have also helped us map a path forward. The research community knows far more today about how to design and execute these complex clinical trials, and we are piloting novel trial designs with a sharper focus on participant adherence to increase the chance that the trial will generate the data needed for effective product development and licensure.

And as important as the PRO2000 data are in supporting the concept that a topical microbicide can prevent HIV infection, new products are needed that can increase the level of protection that was observed in the MTN study. IPM and others are now testing a new generation of microbicide candidates that contain highly potent antiretrovirals (ARVs) that specifically target HIV. These ARV microbicides are based on the same antiretroviral drugs being used successfully in HIV treatment and to prevent mother-to-child transmission of HIV. These next-generation microbicides are following the lead of treatments that have been successfully adapted to life-saving prevention methods for other diseases, including malaria, influenza and pneumonia. Next-generation microbicide candidates are in safety and early efficacy studies in a variety of countries in Europe, North America, and Africa. We need to test these candidate products both as single drugs and in combinations to see which approach is the most viable.

We also know from the contraceptive field that the more choices a woman has to protect herself, the more likely she will be able to use one of them for protection. IPM and others are conducting numerous product acceptability studies in Africa to help determine what types of products women really want and would use. Some women might like a gel used around the time of sex, others a product used once a day or even a vaginal ring that protects for up to 30 days at a time, and still others might prefer a vaginal film. Expanding microbicide formulation options in addition to coitally used gels is a promising next step in HIV prevention.

The need for microbicides remains clear, with 17.7 million women living with HIV globally and thousands more infected every day. And women urgently need prevention options they can initiate and control.

IPM applauds the leadership and ongoing resolve of the national governments that host these studies, the women who volunteer to participate, the donors who provide financial support, private sector partners who contribute promising drugs, our scientific colleagues who lend their expertise, and advocates around the globe who work to ensure that the voices of those who are poor and ill are heard. While the path remains difficult and uncharted, we have good reason to carry on with hope. A comprehensive HIV prevention strategy that includes microbicides is the world's best hope for halting the disease's spread.

For more information on the BufferGel and PRO2000 trial, visit:
<http://www.mtnstopshiv.org/>