



Recent Developments in Microbicide Clinical Trials: A Statement on the Carraguard and PRO-2000/5 HIV Prevention Trials

Dr. Zeda Rosenberg, CEO, the International Partnership for Microbicides

(Feb. 19, 2008) – The Population Council, an international not-for-profit organization that conducts biomedical, social science, and public health research, has now released final results from its Phase III efficacy trial of Carraguard, a vaginal gel being tested to prevent HIV transmission to women during sex. Results from the three-year trial, conducted at three clinical research centers in South Africa, show that while Carraguard had a strong safety profile, it did not prevent HIV infection.

The Carraguard news comes just days after the Microbicides Development Programme (MDP) reported it was closing one arm of its three-arm PRO 2000/5 microbicide trial. The MDP, a partnership of African and European researchers, was acting on the recommendation of its Independent Data Monitoring Committee. The oversight body determined that the arm of the trial using a 2% gel concentration presented “no more than a small chance of showing protection against HIV.” MDP will continue with the other two arms, one with a smaller 0.5% gel concentration and the other with a placebo, with the possibility that 0.5% PRO 2000/5 gel will be effective. These studies are taking place in South Africa, Tanzania, Uganda and Zambia.

These two pieces of information, taken together with a series of disappointing results over the past year from other HIV prevention trials, are a stark reminder that drug development in general is a difficult and unpredictable process, and that the majority of drugs that enter the clinical trial process fail. This is especially true for first-in-class drugs like microbicides. But when success finally does occur, millions stand to benefit.

IPM acknowledges the important work of the two trials’ sponsors, researchers, staff, and almost 14,000 volunteers for their dedication to developing new tools for women to protect themselves from HIV. Their work on behalf of women’s health worldwide should not go unheralded. While IPM did not have a role in the Carraguard and PRO 2000/5 trials, valuable lessons can be gained. All of us working to develop new HIV-prevention tools will carefully examine the lessons of these trials and incorporate them into our efforts to design and conduct the safest, most efficient trials and provide participants with the highest possible standard of care.

The need for microbicides and additional HIV prevention tools remains urgent, and a continued and sustained commitment to research will get us there. Across the globe, 15.4 million women are living with HIV and thousands more become infected every day. New, female-initiated prevention options offer one of the world’s best hopes for halting the disease’s spread.



INTERNATIONAL PARTNERSHIP *for* MICROBICIDES

For its part, IPM remains committed to developing “next-generation” microbicides. Unlike earlier products, next-generation compounds specifically target HIV infection and can be designed in formulations for daily or monthly use, independently of sex. These next generation products, based on the same antiretroviral drugs being used successfully in HIV treatment, are currently in development by IPM and others.

For more information on the Carraguard trial, visit:
<http://www.popcouncil.org/microbicides/Resources.html>

For more information on the PRO 2000/5 trial, visit:
<http://www.mdp.mrc.ac.uk/>