CONTACT: Lisa Rossi
PHONE: +1-412-641-8940
+1-412- 916-3315 (mobile)
E-MAIL: rossil@upmc.edu

MICROBICIDE TRIALS NETWORK STATEMENT ON THE RESULTS OF MDP 301

PITTSBURGH, Dec. 14, 2009 – Earlier this year, at the Conference on Retroviruses and Opportunistic Infections in Montreal, we reported the results of HPTN 035, a Phase IIb study of two vaginal microbicides for preventing the sexual transmission of HIV in women. HPTN 035 was designed to assess the safety of 0.5% PRO 2000 gel and BufferGel and establish whether either product showed sufficient promise for further testing in a Phase III trial or for licensure. We reported that both gels were safe and PRO 2000 reduced the risk of HIV by 30 percent, a finding that, although encouraging, was not statistically significant. The test for statistical significance suggested that there was a one in 10 likelihood that this moderately protective effect may actually have been due to chance. We looked to our colleagues conducting MDP 301, a Phase III study involving nearly 9,400 women, to give a more definitive answer about PRO 2000. As we have learned today, this larger trial has confirmed that PRO 2000 does not offer protection against HIV.

The research team from the U.S.'s Microbicide Development Programme (MDP) is to be commended for its hard work, tenacious spirit and principled approach. The MDP team has demonstrated that large-scale, high-quality microbicide studies can be successfully executed in resource-poor settings. The women who took part in both MDP 301 and HPTN 035 deserve special recognition as well. If not for their dedication and commitment, these two studies could not have been completed.

Although more detailed results are not yet available, we can expect to learn much from a study of MDP's size and caliber, information that well help the entire field work toward identifying safe and effective biomedical prevention strategies. But there is little question that this study marks the end to an era of investigation focused on the early generation, novel nonspecific microbicides. And the results raise little doubt that at this juncture, agents with specific action against HIV, such as antiretroviral drugs, offer the most hope.

Now it is with renewed purpose that we must work to realize the promise of antiretroviral-based prevention. We must not allow our disappointment in the outcome of this study to interfere with our current momentum and progress in pursuing approaches that are applying some of the same drugs used to treat HIV for HIV prevention. We must hope that positive results are within our reach.

# # #

For more information about MDP 301 and HPTN 035, see MTN's fact sheet "What's Next," http://www.mtnstopshiv.org/node/1594. Additional information about HPTN 035 can be found at http://www.mtnstopshiv.org/news/studies/hptn035, and information about MDP 301 can be found at http://www.mdp.mrc.ac.uk/

The Microbicide Trials Network (MTN) *is an HIV/AIDS clinical trials network established in 2006 by the National Institute of Allergy and Infectious Diseases with co-funding from the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the National Institute of Mental Health, all components of the U.S. National Institutes of Health. Based at Magee-Womens Research Institute and the University of Pittsburgh, the MTN brings together international investigators and community and industry partners who are devoted to reducing the sexual transmission of HIV through the development and evaluation of products applied topically to mucosal surfaces or administered orally. More information can be found at www.mtnstopshiv.org.*

Dec. 14, 2009