

For immediate release



Contacts:

Mitchell Warren in Vienna, +1-914-661-1536, mitchell@avac.org
Kay Marshall in New York +1-347-249-6375, kay@avac.org

***AVAC Praises CAPRISA 004 Trial Collaborators and Participants for Historic Study
Trial Confirms Promise of ARV-Based Microbicides***

Vienna, 20 July 2010 – “This is a historic day for HIV prevention research. The CAPRISA 004 results are the first clinical evidence that a microbicide gel can help to prevent sexual transmission of HIV infection,” said AVAC Executive Director Mitchell Warren, reacting to the results of the landmark microbicide trial presented today at the International AIDS Conference in Vienna.

“We believe that the most responsible plan of action now is to quickly and efficiently articulate the sequence of steps necessary for confirmation and follow-up of these results, while also aggressively planning for potential roll-out of a licensable product.”

“It will take time and resources to fully analyze and understand the data, but this proof of concept demands immediate action both in South Africa where there are a range of key, context-specific issues—and on a global level where this new evidence will energize and redirect the microbicide field as well as the broader arena of prevention strategies based on anti-HIV drugs. Simultaneous efforts on many fronts are needed to eventually realize the public health potential suggested by these data.”

“We congratulate the trial sponsors, scientific collaborators, and partners who conducted this trial, and especially want to thank the nearly 900 South African women whose altruism and commitment as trial volunteers made this effort possible. These volunteers and their communities have made an inestimable contribution to HIV prevention research and to the eventual development of new ways for women and men all over the world to protect themselves from HIV. We owe them an enormous debt of gratitude,” Warren said.

“As we move forward in our search for microbicides and other new HIV prevention options, researchers will need the collaboration of tens of thousands more men and women around the world in additional trials. Right now, the VOICE trial is working in four countries, including South Africa, to evaluate both 1% tenofovir gel and oral pre-exposure prophylaxis—this study is more important than ever, as are additional trials that have yet to be planned.”

As the trial team reported in Vienna today, CAPRISA 004 provided the first evidence that the use of the antiretroviral (ARV) drug tenofovir in the form of a vaginal gel can reduce the risk of HIV infection in women. The overall rate of effectiveness reported in the trial was 39 percent. The “test of concept” trial tested the effectiveness of 1% tenofovir gel, used before and after sex, among urban and rural South African women at high risk of HIV via vaginal sex.

“These results move us one step closer to finding much needed new HIV prevention options for women and men,” said Warren. “We look forward to working with the field to further examine the great wealth of data this trial has produced. These data will help guide decisions about further studies needed as well as provide important information to help design implementation programs if additional research indicates that we have a licensable product.”

AVAC calls on the trial sponsors, researchers, funders and others in the field to work quickly, and cooperatively to boldly to translate these findings into development of a scientific action plan to attempt to confirm these results and answer other outstanding questions. Such a

plan must be well resourced and swiftly implemented, and it must ensure that additional supplies of tenofovir gel can be quickly manufactured to meet the needs of follow-up studies.

“As exciting as this result is—and as important as it is to follow it up without delay—the reality is that this product will not be available for widespread introduction tomorrow. Its critical to manage expectations while maintaining urgency. This challenging but necessary work falls on the shoulders of all stakeholders involved in AIDS prevention and treatment. At the same time, we must ensure that all stakeholders reaffirm their commitments to work that will lead to eventual access to effective microbicides for everyone who needs them,” Warren said.

Additional relevant information will also come from the ongoing research on other, related antiretroviral-based prevention strategies in HIV negative people. These include trials of pre-exposure prophylaxis, or PrEP, which is evaluating the use of oral ARVs to reduce HIV risk in HIV negative people. There is also one other ongoing effectiveness trial known as MTN 003, or VOICE, that is evaluating daily use of 1% tenofovir gel (a different dosing strategy from CAPRISA 004) along with oral use of tenofovir or tenofovir/emtricitabine. The positive finding from CAPRISA 004 increases hope that there will be benefit in some of these other trials—but it is no guarantee. Ongoing and additional research is needed to clarify the full potential of ARV-based prevention.

“This is an astonishing scientific achievement and a great boost to the microbicide field. At the same time, the results are complicated, and we will need to work hard to make sure that women and their partners understand what these results do and do not mean for the immediate future and in the long-term,” said Warren. “We are committed to working with communities to understand the results and the next steps.”

“The CAPRISA 004 results add immensely to the drive for a comprehensive response to HIV,” Warren added. “That means ensuring access for all who need it to existing HIV prevention and treatment options, including male and female condoms, behavior change counseling, male circumcision, clean needles, harm reduction and antiretroviral drugs; ensuring continued research to find effective new options, including microbicides, PrEP and vaccines; and planning for integrating these new interventions into combination programs.”

CAPRISA 004 was led by the Centre for the AIDS Programme of Research in South Africa (CAPRISA) at the University of KwaZulu-Natal and FHI and CONRAD in the US, and sponsored by the US Agency for International Development (USAID) and TIA, a biotechnology agency of the South African government’s Department of Science and Technology.

An AVAC report, *A Cascade of Hope and Questions: Anticipating the results of upcoming ARV-based prevention trials* and additional information about CAPRISA 004 and other upcoming results are available online at www.avac.org/caprisa004.

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Founded in 1995 as the AIDS Vaccine Advocacy Coalition, AVAC is an international non-profit organization that uses education, policy analysis, advocacy, and community mobilization to accelerate the ethical development and eventual global delivery of AIDS vaccines and other new HIV prevention options as part of a comprehensive response to the pandemic.