



Advocacy to accelerate ethical research & global delivery of AIDS vaccines and other new prevention options

***AVAC Statement on Phambili and STEP trials
Trial Participant Safety is the Top Priority***

Contact: Mitchell Warren, +1-914-661-1536, mitchell@avac.org

New York and Johannesburg, October 26, 2007 – The AIDS Vaccine Advocacy Coalition (AVAC) issued the following statement with regard to recent announcements about the Phambili AIDS vaccine trial in South Africa.

"We are deeply concerned by and share the disappointment of the field regarding the October 23 announcement that the immunizations would be stopped in the Phambili trial of Merck's Ad5 candidate, and that volunteers in that study would be counseled that receiving the vaccine might have increased their risk of acquiring HIV infection," said Mitchell Warren, AVAC executive director.

"This is a serious setback and heavy blow to the dedicated volunteers, principal investigators, and site staff who have committed their time, energy and optimism to this study. As always, we believe that participant safety is paramount and that where ever doubts arise, monitoring boards and trial sponsors must err on the side of caution.

"At this time, it is not clear whether or not there is definitive evidence that the vaccine did increase participant's susceptibility. In the absence of this information, we must make sure that all participants in all of the trials of the Merck product understand the basis for the counseling messages about the possibility of increased susceptibility to HIV infection. We must also be cautious about leaping to definitive conclusions until the full data sets have been analyzed."

On Tuesday, October 23, the South African AIDS Vaccine Initiative (SAAVI) and the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH) issued press statements stating that the Data and Safety Monitoring Board (DSMB) for the Phambili trial [HVTN 503] had reviewed the available data from the STEP study of the same candidate, which halted immunizations in September, 2007.

As the NIAID press release stated, the DSMB made several recommendations: "The DSMB also recommended that HVTN 503 volunteers be told whether they received the vaccine or placebo, be strongly encouraged to return to their study sites for protocol-related tests, and be counseled about the possibility that those who received the vaccine may have an increased susceptibility to acquiring HIV infections."

"It is very important that the field put forward clear common messages," said Pontiano Kaleebu, AVAC board member, and principal investigator on AIDS vaccine trials at the Uganda Virus Research Institute. "The search for an AIDS vaccine must continue even when there is bad news. To move forward, all of us -- communities, investigators, sites, the media -- must work together to convey accurate messages based on the information available."

Additional data set from the STEP study will be released in a public discussion on November 7, 2007, at HIV Vaccine Trial Network meeting in Seattle, Washington. This meeting will include data on rates and timing of infection from the second 1500 volunteers enrolled in the STEP study.

"It is hoped that exploration of this additional data from STEP will add to our understanding of what happened in that trial, and shed additional light on many questions, including whether vaccine recipients did indeed have increased risk of acquiring HIV," said Warren.

###

About AVAC

Founded in 1995, the AIDS Vaccine Advocacy Coalition (AVAC) is a non-profit, community- and consumer-based organization that uses public education, policy analysis, advocacy and community mobilization to accelerate the ethical development and global delivery of AIDS vaccines and other HIV prevention options. To help assure its independence, AVAC does not accept funding from government or pharmaceutical industry sources. For more information, visit www.avac.org.