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**Contact:**

Mitchell Warren +1 (212) 367-1279 or +1 (914) 661-1536, [mitchell@avac.org](mailto:mitchell@avac.org)

**AIDS Vaccine Advocacy Coalition Voices Disappointment in Trial Result  
*Applauds Merck's Leadership and Calls for Reinvigorated Effort to Design and Test AIDS Vaccines***

*New York, September 21, 2007* – The AIDS Vaccine Advocacy Coalition (AVAC) released the following statement from Executive Director Mitchell Warren about the announcement that vaccinations have been discontinued in the STEP Study, a test-of-concept trial of the MRK-Ad5 AIDS vaccine candidate developed by the Merck Research Laboratories:

“Today’s announcement about the STEP Study is a deep disappointment and a scientific setback for the AIDS vaccine field. However, it must be seen for what it is: the failure of a product to show efficacy in a specific trial. Clinical testing of AIDS vaccines is a scientific process and, while this is a disappointment, it is in no way the end of the search for an AIDS vaccine.

“These data are certainly not the ones that we had hoped for. The entire HIV vaccine field, including AVAC, had been looking to STEP and its companion Phambili trial in South Africa, to provide initial evidence of vaccine-related benefits. Even as the data disappoint, we also note the success of the STEP Study trial design in providing a swift answer to the critical question of whether or not the vaccine provided any benefits. A successful clinical trial is one that produces a scientifically accurate result. It may not be the result you had hoped for, but it answers questions that help the field move forward.

“We applaud Merck’s tremendous leadership on HIV vaccine research. The company has set an example for the field, taking on one of the most important health technology challenges of our time. Merck and its collaborator, the US NIH-funded HIV Vaccine Trials Network, have been committed, strategic and willing to take risks at every stage of evaluating MRK-Ad5, and they must be commended for this. AVAC also recognizes the contributions of the thousands of volunteers in these trials. Their altruistic involvement makes HIV vaccine research possible. It is essential to build on what has been learned here and proceed with further research as rapidly as possible. Millions of lives are at stake.

“In the next weeks and months the AIDS vaccine field will need to make carefully-considered decisions about whether to move forward with planned trials of related vaccine strategies, and how to proceed with the Phambili trial, which has paused immunizations and enrollment. AVAC is committed to working with many other stakeholders in the AIDS vaccine field and in other areas of AIDS prevention research to ensure that these discussions are thoughtful, transparent, and clearly communicated to global audiences.

“These results do not change our fundamental view. Developing an AIDS vaccine will require a series of large-scale human trials in many different countries over a number of years. These trials need to be designed to produce clear results and to design better candidates in the future. This research must be complemented by ongoing studies of other new biomedical prevention strategies, and by full-scale, fully-funded implementation of proven prevention and treatment strategies.”

### ***About the STEP Study***

An interim analysis of data from the study, involving over 3,000 people testing an adenovirus-based vaccine (MRK-Ad5) developed by the Merck Research Laboratories, showed no efficacy in protecting against new infections or in reducing viral load in people who received the vaccine and went on to become infected. The study was scheduled to end in 2009. Periodic reviews of data by an independent monitoring board are part of the clinical trials process, and the study was halted on the recommendation of the STEP Study monitoring board after a regularly-scheduled review.

There have been two previous efficacy trials of an AIDS vaccine candidate, called AIDSVAX. Both of these studies took more than five years from launch to announcement of the finding—that the candidate did not protect against infection. The STEP Study enrolled its first participant in December 2004, and we have a definitive answer less than three years later. Getting swift, precise answers about candidates is crucial for the field. In this sense, the STEP Study fulfilled its purpose—as disappointing as the results may be.

One reason for this efficiency is that both STEP and its companion trial Phambili, which tested the candidate in South Africa, were designed as “test-of-concept” trials, to give an initial answer about vaccine benefits in a relatively abbreviated timeframe. The STEP Study met its enrollment targets and its endpoint goals within the timeframe specified by the trial planners.

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### ***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](http://www.avac.org).