



HIV VACCINE
TRIALS NETWORK

News Release

FOR IMMEDIATE RELEASE

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Vaccination and Enrollment Are Discontinued in Phase II Trials of Merck's Investigational HIV Vaccine Candidate

Interim Analysis of STEP Study Shows Vaccine was not Effective

WHITEHOUSE STATION, N.J., and Seattle, Sept. 21, 2007 -- Vaccination in a phase II clinical trial of Merck & Co., Inc.'s investigational HIV vaccine (V520) is being discontinued because the vaccine was not effective. The announcement was made today by the co-sponsors of this clinical trial, Merck & Co., Inc., and the HIV Vaccine Trials Network (HVTN), which is funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the U.S. National Institutes of Health.

The trial, called STEP, was an international phase II "test of concept" trial in uninfected volunteers at high risk for acquiring HIV infection. The independent Data Safety Monitoring Board (DSMB) for STEP reviewed safety data and results of an interim efficacy analysis of the study, and recommended that vaccination be discontinued because the STEP trial will not meet its efficacy endpoints. Study investigators have been instructed to discontinue vaccinating volunteers in this study and to monitor them in accordance with the study protocol. Enrollment and vaccination in a second Phase II trial of this vaccine being conducted by the HVTN in South Africa called Phambili, and two additional Phase I trials, have been discontinued. The DSMB for the Phambili trial will evaluate the available data.

The Merck vaccine candidate is a mixture of three components, each made with a weakened version of a common virus (adenovirus type 5), that serves as a carrier, or delivery vector, along with three synthetically produced HIV genes known as *gag*, *pol* and *nef*.

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The STEP study (HVTN 502, Merck V520 Protocol 023) was a multicenter, randomized, double-blind, placebo-controlled phase II test-of-concept clinical trial. The trial enrolled 3,000 HIV-negative volunteers from diverse backgrounds between 18 and 45 years of age at high risk of HIV infection.

The study evaluated two primary efficacy endpoints: whether the vaccine prevented HIV infection and whether the vaccine reduced the amount of virus in those who developed infection. As planned, an interim efficacy analysis was conducted in the approximately 1,500 volunteers expected to have the best response to the vaccine because they had low levels of pre-existing immunity to adenovirus 5.

The vaccine did not prevent infection: in volunteers who received at least one dose of the three-dose vaccine series, 24 cases of HIV infection were observed in the 741 volunteers who received vaccine and 21 cases of HIV infection were observed in the 762 participants in the placebo group. In the subgroup who had received at least two vaccinations and who were HIV negative for at least the first 12 weeks of the trial, 19 cases of HIV infection were observed in the 672 volunteers who received vaccine and 11 cases were observed in the 691 volunteers who received placebo. In addition, the vaccine did not reduce the amount of virus in the bloodstream of those who became infected; HIV RNA levels approximately 8 to 12 weeks after diagnosis of infection were similar in the vaccine and the placebo arms. The geometric means of the HIV RNA levels in the blood of infected individuals, the standard measure of ongoing HIV replication, were approximately 40,000 copies/mL in the vaccine group and approximately 37,000 copies/mL in the placebo group. Additional analyses will be conducted on the entire study population and will be shared with the scientific community.

Study volunteers were followed for approximately 13 months. Overall adverse event rates were generally similar among the two groups, except for a higher rate of local injection-site related reactions in the vaccine group.

"We share in the disappointment of the research and HIV communities today. Sadly, developing an effective AIDS vaccine remains one of the most challenging tasks facing modern medicine," said Peter S. Kim, Ph.D., president, Merck Research Laboratories. "Merck's 20-year HIV research program has led to improved scientific understanding of HIV and to true breakthrough medicines. We are committed to studying the data closely and sharing it with the scientific community to inform the on-going search for an effective HIV vaccine."

"HVTN is a global network of scientists, staff and community members whose mission is to speed the rapid development of a safe and effective preventative HIV vaccine," said Larry Corey, M.D., principal investigator of the HVTN. "This trial was the first test of concept trial that provided

us information on this vaccine more quickly and efficiently than with a traditional Phase III design. While we are very disappointed that this vaccine candidate did not demonstrate protection, the data from this trial will provide critical insights into this disease and future vaccine development."

"This is a huge disappointment for all of us who have been involved in the search for an HIV vaccine," said Glenda Gray, M.D., principal investigator of the HVTN sponsored Phambili trial. "HIV is ravaging our communities, and all the scientists, participants and communities involved in HIV vaccine studies have been affected by this epidemic. The scientific community must continue the race to find a vaccine to help secure an HIV free generation for the future."

The Merck adenovirus-based vaccine used a cell-mediated immune response approach; it was hypothesized that the HIV genes in the vaccine would stimulate the body to generate an HIV-specific immune response through the body's own CD8 T-cells, which become programmed to recognize and kill HIV infected cells.

Adenoviruses are among the causes of common cold; the type 5 adenovirus used in this investigational vaccine had been modified so that it was unable to replicate and could not cause a cold. Also, because the vaccine did not contain live HIV and contained only three HIV genes, volunteers could not become infected with HIV from the vaccination. This vaccine had previously been tested in several smaller clinical trials and was found to be generally well tolerated and capable of inducing significant levels of HIV-specific cell-mediated immune responses.

STEP included multiple clinical trial sites in North and South America, the Caribbean and Australia, where HIV subtype B, the subtype of HIV from which the HIV genes included in the vaccine, is predominant. Half the study participants received three doses of the vaccine over six months, while the other half were given three doses of a placebo. The first volunteer enrolled in the study in December 2004, and enrollment was completed in March 2007.

The second phase II trial of this vaccine candidate, the Phambili trial, (HVTN 503, Merck V 520 Protocol 026) was begun in 2007 in South Africa by the HVTN to explore whether Merck's vaccine would be effective at preventing infection, reducing viral levels, or both, from HIV subtype C, which is more common in southern Africa.

About Merck and Merck's HIV research program

Merck's efforts to develop investigational treatments and a vaccine against HIV/AIDS have been under way for more than 20 years and continue today; our HIV research program began in 1986. Merck scientists were the first to characterize the role of HIV protease in the HIV life cycle and to publish the crystal structure of the HIV protease enzyme, which helped the research community design protease inhibitors to block HIV infection by this mechanism. In the

1990s, Merck scientists discovered the protease inhibitor, CRIXIVAN[®] (indinavir sulfate), and the non-nucleoside reverse transcriptase inhibitor, STOCRIN[®] (efavirenz). In addition, on September 5, 2007, an advisory committee to the Food and Drug Administration unanimously recommended approval of ISENTRESS[™] (raltegravir), Merck's investigational integrase inhibitor for the treatment of HIV infection. The FDA is not bound by the committee's recommendation but takes its advice into consideration when reviewing investigational medicines and vaccines.

Merck & Co., Inc. is a global research-driven pharmaceutical company dedicated to putting patients first. Established in 1891, Merck currently discovers, develops, manufactures and markets vaccines and medicines to address unmet medical needs. The Company devotes extensive efforts to increase access to medicines through far-reaching programs that not only donate Merck medicines but help deliver them to the people who need them. Merck also publishes unbiased health information as a not-for-profit service. For more information, visit www.merck.com.

About the HIV Vaccine Trials Network

The HVTN is an international collaboration of scientists and institutions whose goal is to accelerate the search for an HIV vaccine by sharing trial results and facilitating parallel, concurrent testing. The HVTN is a unique hybrid that combines the depth and diversity of the academic community and the flexibility of a commercial drug company. Working with industry and government, the HVTN seeks to expedite and coordinate the trial process, advancing vaccine candidates and building a body of knowledge about HIV vaccine trials.

The HIV Vaccine Trials Network is supported through a cooperative agreement with the National Institute of Allergy and Infectious Diseases (NIAID), which is a component of the U.S. National Institutes of Health (NIH). The Network and NIAID have a close, cooperative working relationship, with shared attention to the intellectual and scientific issues. The Network's headquarters are at Fred Hutchinson Cancer Research Center in Seattle, Washington.

Merck forward-looking statement

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations and involve risks and uncertainties, which may cause results to differ materially from those set forth in the statements. The forward-looking statements may include

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statements regarding product development, product potential or financial performance. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect Merck's business, particularly those mentioned in the risk factors and cautionary statements in Item 1A of Merck's Form 10-K for the year ended Dec. 31, 2006, and in its periodic reports on Form 10-Q and Form 8-K, which the company incorporates by reference.

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