



RV 144

## Sponsor's Press Release

**Contact:** Lisa Reilly, MHRP, +1 301-251-5070  
Mary Jane Walker, Hill and Knowlton, +1 212-885-0464

### **HIV Vaccine Study First to Show Some Effectiveness in Preventing HIV**

24 September 2009 (Rockville, MD, USA)—A Phase III clinical trial involving more than 16,000 adult volunteers in Thailand has demonstrated that an investigational HIV vaccine regimen was safe and modestly effective in preventing HIV infection. According to final results released by the trial sponsor, the U.S. Army Surgeon General, the prime boost combination of ALVAC<sup>®</sup> HIV and AIDSVAX<sup>®</sup> B/E lowered the rate of HIV infection by 31.2% compared with placebo.

"This is the first HIV vaccine candidate to successfully reduce the risk of HIV infection in humans. We are very excited and pleased with the outcome of this trial and congratulate all those who participated in it," said Lieutenant General Eric Schoomaker, Surgeon General, U.S. Army. "In addition, this study is an outstanding example of international and interagency collaboration involving many partners from the Thai and U.S. governments, private companies, non-profit organizations and volunteers."

In the final analysis, 74 placebo recipients became infected with HIV compared to 51 in the vaccine regimen arm. The efficacy result is statistically significant. The vaccine regimen had no effect on the amount of virus in the blood of volunteers who became HIV-infected during the study. More detailed results of this study will be presented next month at the AIDS Vaccine Conference, October 19 through 22 in Paris, France.

This finding has important implications for the design of future HIV vaccines and how they are tested, however additional research is needed to better understand how this vaccine regimen reduced the risk of HIV infection. Given the significant threat of HIV infection worldwide, an efficacious vaccine is urgently needed, as part of a broader prevention effort to help control the epidemic.

Collaborating partners on this study, referred to as RV144, include the U.S. Army, the Thai Ministry of Public Health, the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, sanofi pasteur, and Global Solutions for Infectious Diseases (GSID). The collaborators are already working with external experts to determine the need for additional studies on this vaccine regimen and consider the

impact of this study's findings on other HIV vaccine candidates.

“These results show that development of a safe and effective preventive HIV vaccine is possible, “ said Colonel Nelson Michael, Director, Division of Retrovirology, Walter Reed Army Institute of Research and Director, U.S. Military HIV Research Program (MHRP). “While these results are very encouraging, we recognize that further study is required to build upon these findings.”

Colonel Jerome Kim, Deputy Director (Science), MHRP and the HIV vaccines product manager for the U.S. Army added that, “knowledge gained through this study will be used to accelerate future study design and testing as researchers continue the search for a safe, globally-effective HIV vaccine.”

The U.S. Army would like to thank the more than 16,000 Thai men and women who consented to participate in this trial and the efforts of the Thai Ministry of Public Health and all collaborators for their hard work in achieving this important milestone.

### **RV144 Phase III Trial Background**

RV144 tested a prime-boost vaccine strategy that combined two vaccines based on strains (subtypes) of HIV that circulate in Thailand. The first, or “prime” vaccine, known as ALVAC HIV, was developed by sanofi pasteur and the booster vaccine, AIDSVAX B/E, was originally developed by VaxGen and is now licensed to Global Solutions for Infectious Diseases.

The proof-of-concept study, which began in 2003, was designed to evaluate the vaccine strategy's ability to prevent HIV infection, as well as its ability to reduce the amount of HIV in the blood of those who became infected after they enrolled in the study.

More than 16,000 HIV-negative men and women between the ages of 18 to 30 participated in the study; half of these participants received the prime-boost vaccine regimen and half received placebo. Volunteers received vaccinations over the course of six-months and were followed for an additional three-years. Before agreeing to participate, all volunteers were informed of the potential risks associated with receiving the experimental vaccine regimen used in this study and consented to participate in the study. Volunteers continued to receive an HIV test every six-months for three-years following vaccination, in addition to counseling on how to prevent becoming infected with HIV.