

## Phase III Trial-Thailand

U.S. Army and the Thailand Ministry of Public Health join forces to develop a safe and effective preventive HIV vaccine

- **World's largest HIV vaccine trial ever conducted**
- **Tested a "prime-boost" vaccine strategy comprised of two investigational vaccines**
- **Successful international collaboration involving more than 16,000 Thai volunteers**

### Introduction

The Thai Phase III HIV vaccine clinical trial, also known as RV 144, tested the "prime-boost" combination of two vaccines: ALVAC® HIV vaccine (the prime), and AIDSVAX® B/E vaccine (the boost). The vaccine combination was based on HIV strains that commonly circulate in Thailand.

RV 144 was designed to test the vaccine strategy's ability to prevent HIV infection, as well as its ability to reduce the amount of HIV in the blood (viral load) of those who became infected after they enrolled in the study.

The study was made possible by an international collaboration involving numerous partners from the Thai and U.S. governments, private companies, non-profit organizations and more than 16,000 volunteers.

### Study Background

With the emergence of an explosive HIV epidemic in Thailand in the early 1990s, Army researchers helped to characterize the heterosexual epidemic, isolated Thai viruses, and made these sequences available to companies developing HIV vaccines. Army researchers have had a long-standing relationship with the Royal Thai Army, Thai Ministry of Public Health and other Thai vaccine experts, and together they developed a plan to test this candidate vaccine in Thailand.

### Strong Safety Record

An international Data and Safety Monitoring Board met eight times since trial initiation and did not identify any safety concerns.

The study vaccines did not cause HIV infection because they are not made from and do not contain the entire virus, either live or killed.

### Study Volunteers

- 16,402 non-infected volunteers (18-30 years old) at average risk of HIV infection; half received the prime-boost combination of vaccines/half received a placebo.
- Vaccinations ended in July 2006, and volunteers received an HIV test every six-months for three-years.
- Study volunteers received counseling on how to prevent becoming infected with HIV at the beginning of the study and every six months after the start of the trial, for a total of three and a half years.
- Before agreeing to participate, all volunteers were informed of and consented to the potential risks associated with receiving the experimental vaccine combination.
- Volunteers who acquired HIV infection during the trial were given free access to HIV care and treatment, and were offered follow-up in a separate study.

### Global Significance

The HIV pandemic is an unprecedented global crisis. An HIV vaccine continues to be the best hope for ending the HIV pandemic. The U.S. Army is committed to developing a globally effective HIV vaccine to protect U.S. and allied troops from infection and to support the U.S. National Security Strategy by reducing the global impact of the disease.

HIV vaccine research—like all scientific research—is an iterative process. The knowledge gained through this clinical trial will be used to design future studies.

**October 2003**

Study begins in Thailand.

**June 2009**

Trial concluded on June 30, 2009.

**September 2009**

Results announced in September.

## Study Sponsor

The study is sponsored by the U.S. Army and is conducted by the Thailand Ministry of Public Health.

The U.S. Military HIV Research Program provides overall project leadership, and the U.S. Army Medical Component – Armed Forces Research Institute of Medical Sciences (AFRIMS) helps execute the trial in Thailand on behalf of the Sponsor.

AFRIMS is a Special Foreign Activity of Walter Reed Army Institute of Research (WRAIR) hosted by the Royal Thai Army and staffed by American and Thai personnel. For almost 50 years, AFRIMS has been America's premier Asian site to study infectious diseases of military importance.

This study was supported by a cooperative agreement with the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc.



The U.S. Military HIV Research Program (MHRP)—centered at the Division of Retrovirology, WRAIR—is at the forefront of the battle against HIV/AIDS to protect U.S. troops from infection and reduce the global impact of the disease.

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## Special Thanks

The U.S. Army would like to thank the Thai men and women who participated in this trial and whose high rate of participation has been essential to its success.

### STUDY

- RV144: A Phase III Trial of Aventis Pasteur Live Recombinant ALVAC® HIV (vCP1521) Priming with VaxGen gp120 B/E (AIDSVAX® B/E) Boosting in HIV-uninfected Thai Adults

### SPONSOR

- U.S. Army Surgeon General

### FUNDING

- Division of AIDS, National Institutes of Allergy and Infectious Diseases, NIH
- U.S. Army Medical Research and Materiel Command

### LOCATION

- Rayong and Chon Buri Provinces, Thailand
- 47 health centers (screening and tracking)
- 8 clinical sites

### VACCINE MANUFACTURERS

- Global Solutions for Infectious Diseases-AIDSVAX B/E
- sanofi-pasteur-ALVAC-HIV vCP1521

*\*Global Solutions for Infectious Diseases (GSID) holds the intellectual property rights to AIDSVAX B/E originally developed and previously owned by VaxGen.*

### STUDY EXECUTION

- Department of Disease Control, Thai Ministry of Public Health (MOPH)
- Vaccine Trials Centre, Faculty of Tropical Medicine, Mahidol University
- Data Management Unit, Faculty of Tropical Medicine, Mahidol University
- Chon Buri and Rayong Provincial Chief Medical Offices, MOPH
- Armed Forces Research Institute of Medical Sciences; Thai Component and U.S. Component (USAMC-AFRIMS)
- Division of Retrovirology, WRAIR, MHRP
- U.S. Army Medical Materiel Development Activity, U.S. Army Medical Research and Materiel Command

It is important to note that a vaccine must be seen as part of a comprehensive approach to prevention of HIV infection. The true public health benefits of any vaccine, and particularly of an experimental vaccine that has not yet been licensed, can only be realized if vaccine recipients continue to control HIV risk-taking behavior.