



## **Prime-Boost Vaccine Study Shows Modest Effect in Preventing HIV**

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**South San Francisco, Calif. – September 24, 2009** – Global Solutions for Infectious Diseases (“GSID”) announced today that a Phase III clinical trial of an investigational HIV vaccine regimen has been shown to be safe and modestly effective in preventing HIV infection. The double-blind, placebo controlled study was conducted in Thailand among more than 16,000 volunteers.

The clinical trial (RV 144), the world’s largest study of an HIV/AIDS vaccine regimen, demonstrated that the combination of a priming vaccine developed by sanofi pasteur (ALVAC®HIV vCP1521) and GSID’s boosting vaccine (AIDSVAX®B/E) reduced HIV infection in a community-based population by 31.2% compared with placebo. In the final analysis, 74 placebo recipients became infected with HIV compared to 51 vaccine recipients. The efficacy result is considered statistically significant with a p-value of 0.04 and a 95% confidence interval having a lower bound greater than zero.

Additional research will be required to clarify the public health benefits of this outcome, including whether boosters would be needed and whether the vaccine combination would yield the same results against different strains of the virus found in other parts of the world. One of the most critical steps now would be to manufacture new lots of AIDSVAX for a variety of possible future studies in combination with ALVAC. GSID would make AIDSVAX at a qualified contract manufacturer.

“As the first HIV vaccine trial to demonstrate some level of reduced infection among the entire trial population, this is an encouraging step forward in the struggle to develop an effective HIV/AIDS vaccine,” said Donald Francis, M.D., D.Sc., GSID’s executive director. “This trial will provide researchers with valuable data and insights to continue the development of a vaccine that can hopefully one day eradicate this terrible disease.” He congratulated the Thai Ministry of Public Health and the U.S. Army who collaborated to make this trial successful, and further expressed his appreciation to the National Institute of Allergy and Infectious Diseases (NIAID) for its scientific and financial support.

The vaccine combination tested in Thailand was developed based on the strains of HIV that circulate in that country. Separate versions of the vaccine may have to be manufactured and developed for HIV strains that predominate elsewhere in the world, including North America. The Thai study, which began in 2003, was designed to test the vaccine regimen'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 during the trial. The study did not show a statistically significant result in reducing the viral load in the HIV-infected volunteers.

After initial development at Genentech, the AIDSVAX technology was transferred to VaxGen Inc., which completed two Phase III trials of AIDSVAX alone in high risk populations in Thailand, North America and Europe in 2003. Both trials did not show a statistically significant reduction in HIV infection. GSID obtained certain intellectual property and manufacturing rights related to AIDSVAX in 2008.

### **Thai Trial Summary**

The trial included non-infected volunteers between 18 and 30 years of age who were at average risk of HIV infection. Approximately 40% of the volunteers were women. Volunteers who acquired HIV infection during the trial were given free access to HIV care and treatment, including highly active antiretroviral therapy (HAART), according to the guidelines of the Thai Ministry of Public Health.

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

“This study is encouraging not only for the outcome but for the extraordinary cooperation among the numerous entities,” Francis said. “We look forward to continuing our collaboration with our partners in Thailand, the U.S. government and the private sector to advance this product. I also want to offer my personal gratitude to the more than 16,000 Thai volunteers who stepped forward to participate in this study and stayed with it for six years. They are the real heroes today.”

### **About GSID**

Global Solutions for Infectious Diseases is dedicated to expanding the development of low-cost effective tools for the diagnosis and prevention of infectious diseases afflicting the developing world. As a non-profit organization, GSID focuses its development efforts in parts of the world where these tools are needed the most. Our leadership has extensive experience both in private sector product development and field application of vaccines in the developing world, and is therefore able to provide guidance and support to organizations such as private foundations, public-private partnerships and private sector companies dedicated to solving global public health issues. For more information, please see [www.gsid.org](http://www.gsid.org).