

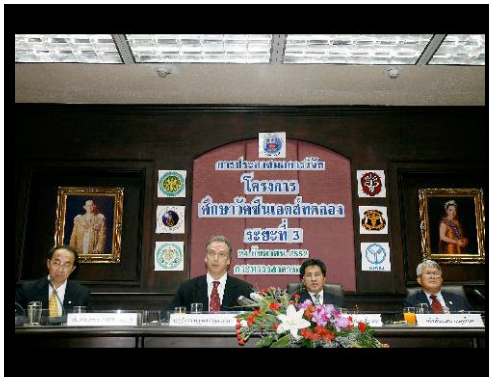
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HIV Vaccine Shows Promise for First Time, Study Shows (Update3)

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By Simeon Bennett



Sept. 24 (Bloomberg) -- An experimental vaccine prevented HIV infections for the first time, a breakthrough that eluded scientists for a quarter century.

A U.S.-funded study involving more than 16,000 volunteers in Thailand found that a combination of ALVAC, made by Paris-based **Sanofi-Aventis SA**, and AIDSVAX, from VaxGen Inc., of South San Francisco, cut infections by 31.2 percent in the people who received it compared with those on a placebo, scientists said today in Bangkok. Neither vaccine had stopped the virus that causes AIDS when tested separately in previous studies.

The finding represents a revival in a campaign that appeared to stall just two years ago when use of **Merck & Co.**'s experimental Ad5 vaccine boosted some people's chances of infection in a study. The latest result will transform future research, said **Mitchell Warren**, director of the New York-based AIDS Vaccine Advocacy Coalition.

"Wow," said Warren, who was not involved in the study, in a telephone interview today. "We are in a new place in the search for an AIDS vaccine. It's safe to say that the scientific community is caught off-guard."

The findings don't mean the vaccine can be delivered worldwide, because of unanswered questions about how the vaccine worked and the fact that it was designed using HIV strains that are specific to Thailand, said **Anthony Fauci**, director of the National Institute of Allergy and Infectious Disease in Bethesda, Maryland. It will take years of research before a vaccine might be ready for U.S. approval, he said.

A Beginning

"This is the beginning of the effort," Fauci said in a conference call with reporters today. "It's opened up the door for us to ask some very important fundamental scientific questions as well as some clinical questions."

VaxGen shares rose 13 cents, or 19 percent, to 82 cents at 10:11 a.m., after earlier reaching \$1 in over-the-counter trading. Sanofi shares declined 57 cents to 50.30 euros in Paris.

The Thailand **study** looked at whether different infection-fighting strategies devised by Sanofi and **VaxGen** could be combined into a two-pronged attack. It was conducted by Thailand's Ministry of Public Health over six years, and led by researcher Supachai Reks-Gnarm.

"What is exciting is that this has provided a proof of concept, that we can do this," said **Cate Hankins**, chief scientific officer at UNAIDS, the United Nations AIDS-fighting agency. "Anything is possible now, it feels. It is a scientific breakthrough," Hankins said by phone from London.

Canarypox Virus

Sanofi's ALVAC uses a canarypox virus that's been disabled so it doesn't cause sickness in humans to smuggle

three HIV genes into the body. It's designed to coax the immune system to make so-called T-cells, protectors that hunt and kill infection deep inside the body.

The AIDSVAX shot contains an HIV protein called **gp120** that's used by the virus to enter human cells. It is designed to encourage the body to produce neutralizing antibodies to destroy HIV viruses before they can infect healthy cells.

The search for a vaccine to prevent HIV has eluded scientists since the early 1980s. AIDS, the syndrome linked with HIV, infects about 6,800 new people globally every day. While there are treatments for HIV that limit the virus in the body, holding AIDS at bay for years, there is no cure.

First Evidence

"This is the first concrete evidence, since the discovery of the virus in 1983, that a vaccine against HIV is eventually feasible," **Michel DeWilde**, senior vice president of research at Sanofi Pasteur, the French drugmaker's vaccine arm, said in a statement today.

An international test of the Ad5 vaccine made by Whitehouse Station, New Jersey-based Merck in about 3,000 people was halted in September 2007, when 49 HIV infections occurred among those who received it compared with 33 among those who got placebo shots. That suggested the product may have raised HIV risk among people exposed to blood or semen containing the virus.

In 2004, a group of U.S. AIDS researchers said in a letter to the journal **Science** that the combination trial would probably disappoint, and shouldn't be allowed to proceed because of the failure of the two previous studies.

Highest HIV Rates

In a telephone interview from Oxford, England, before the results were reported, **Marie-Paule Kieny**, director of the World Health Organization's Initiative for Vaccine Research in Geneva, said, "I don't think there is a lot of expectation that the efficacy of this vaccine will be very high. Any hint towards identifying something which is protective in humans would be very good news," she said.

The researchers enrolled volunteers in Thailand's Chon Buri and Rayong provinces, which have the nation's highest rates of HIV, according to the study Web site.

Subjects were given four doses of the ALVAC vaccine and two of the AIDSVAX shot over six months, then monitored for three years. They were also given advice on safe sex. There were no serious side effects, the researchers said.

Of those who received the vaccine, 51 became infected with HIV, compared with 74 who received a placebo, the researchers said. Those in the study who became infected with HIV during the trial were given free access to treatment.

In another finding, the vaccine failed to reduce the amount of virus in the blood of subjects who became infected. Researchers had hoped that if the vaccine didn't prevent infections, it would at least cut the virus to levels so low it couldn't be transmitted.

Modest Results

"Although the results were modest, with an efficacy of 31.2 percent, this is a very important scientific advance, and gives us hope that a globally effective HIV vaccine may be possible in the future," said Jerome Kim, a deputy director of science at the Walter Reed Army Institute of Research, which sponsored the trial. "It has already caused us to change some of our ideas," Kim told reporters.

The researchers don't understand exactly how the vaccine prevented infections or why it didn't reduce viral load.

"We need to find out a lot more about how it went about reducing HIV risk," said UNAIDS's Hankins. "There's a whole slew of studies being planned now and meetings being planned to discuss the significance of the results, and to go into detail on the data."

The same vaccine may not necessarily have the same effect in other parts of the world, such as Africa, where different strains of HIV circulate, Hankins said.

VaxGen, spun off in 1995 from South San Francisco, California-based biotech company **Genentech Inc.**, stopped developing AIDSVAX in 2003 after a trial showed it didn't prevent people from getting HIV. The **Global Solutions for Infectious Diseases**, a South San Francisco-based non-profit organization, acquired the rights to the product.

The Thailand trial was funded by the National Institute of Allergy and Infectious Diseases, the **National Institutes of Health** and the U.S. Army Medical Research and Materiel Command.

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