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CDC UPDATE

CENTERS FOR DISEASE CONTROL AND PREVENTION

NCHSTP National Center for HIV, STD & TB Prevention

February 1999

Contact: NCHSTP Office of Communications, (404) 639-8895

Testing a Vaccine Designed to Help Curb the Devastating Toll of HIV in the Developing World

CDC Supports Thai Health Officials and VaxGen in Collaborative Effort

It is estimated that over 30 million individuals worldwide are infected with HIV–the vast majority of whom live in the developing world.[1] One country in particular, Thailand, has experienced a rapidly escalating and severe HIV epidemic since 1988. Among the 60 million inhabitants of Thailand, as many as 800,000 people are currently believed to be living with HIV.

Despite innovative and persistent prevention efforts, HIV continues to spread rapidly, particularly among Thailand's population of injection drug users (IDUs). Methadone treatment, education and counseling on HIV prevention, and easy access to sterile needles have certainly helped to slow the epidemic. Yet, among IDUs in Bangkok, 6% continue to become infected each year. In addition to being one of the nations most severely affected by HIV, Thailand has emerged as one of the nations most committed to ending its toll.

To address the urgent need for an HIV vaccine, Thai officials have been working with the World Health Organization, the Joint United Nations Program on HIV/AIDS (UNAIDS), the International AIDS Vaccine Initiative (IAVI), the Government of Japan, the U.S. National Institutes of Health (NIH), the U.S. Department of Defense, various universities, and the Centers for Disease Control and Prevention (CDC) since 1991 to prepare for HIV vaccine efficacy trials. In February 1999, Thailand became the first developing nation to announce a Phase III vaccine field trial. A Phase III trial is done to determine if a vaccine is effective in protecting against infection or disease and is an important step in the evaluation process leading to licensure.

AIDSVAX Phase III trial in Thailand

As part of the Thai National Plan for HIV vaccine research, the Bangkok Metropolitan Administration (BMA) is leading the three-year collaborative research trial to evaluate the ability of AIDSVAX to prevent HIV infection among uninfected IDUs in Bangkok, Thailand. AIDSVAX was developed by VaxGen, a U.S. vaccine developer. BMA is conducting the trial in conjunction with VaxGen, the Mahidol University Faculty of Tropical Medicine in Bangkok, and the HIV/AIDS Collaboration (a longstanding research collaboration between the Thai Ministry of Public Health and CDC).

The trial is being conducted among uninfected IDUs attending 17 drug treatment clinics in Bangkok. The design is a randomized, double-blind, placebo-controlled trial in which half of the 2,500 volunteers receive the AIDSVAX vaccine and the other half receive placebo injections which do not include the vaccine. Neither the researchers nor the participants know which participants are in each half of the trial.

To guard against the relaxation of preventive behaviors, all volunteers receive extensive counseling on how to protect themselves against HIV infection, as well as explicit warnings that this vaccine may not protect them from infection. To further ensure that trial participants are not inadvertently placed at any risk, the trial design, as well as all procedures and protocols for study recruitment and counseling, have received extensive scientific and ethical review by Institutional Review Boards and ethical committees of all involved agencies, both the Thai and U.S. government, and the Joint United Nations Program on HIV/AIDS.

About AIDSVAX

AIDSVAX is a "bivalent" vaccine, meaning it is composed of gp120 proteins found on the outer envelope of two strains of HIV. The version of the vaccine being tested in Thailand is designed to induce antibodies to HIV-1 subtypes B and E, the subtypes of HIV most common in South East Asia and the Pacific Rim. VaxGen is currently evaluating another version of AIDSVAX designed to protect against strains common in North America among 5,000 volunteers in multiple sites throughout the United States. Thai health officials played a leading role in acknowledging the critical need for a vaccine designed for use in Thailand to protect against strains of both subtypes B and E. Early reports from several smaller trials of AIDSVAX in Thailand and the United States, involving about 2,000 persons, have shown the vaccine to be safe and capable of inducing antibodies against these strains of HIV.

U.S. Vaccine Research

Although AIDSVAX is the first vaccine to move to Phase III trials in a developing country, as well as in the United States, it is only one of a series of vaccines that are in various stages of the development process. The National Institutes of Health (NIH) is the agency responsible for coordinating the simultaneous evaluation of multiple vaccine candidates in the United States.

CDC's Role in Vaccine Research and Evaluation
Maintaining Progress in Prevention as We Strive for New Solutions

CDC is the United States' lead federal agency for prevention, including HIV prevention. CDC has nearly two decades experience in designing and evaluating programs to reduce the spread of HIV among populations at risk. Additionally, the agency has a long history of vaccine development and evaluation with other diseases (measles, hepatitis B, and polio). CDC shares the ultimate goal of all of those working to stop the HIV and AIDS epidemic–a vaccine to prevent infection. As we work toward this goal through this and other vaccine trials, it is critical that we not endanger progress already made in HIV prevention and that neither individuals involved in or outside of studies abandon safer sex and drug-related behaviors proven to prevent infection.

CDC's Role in the Thailand Trial

CDC's primary role in the Thailand trial is two-fold. First, continuing a longstanding research collaboration, CDC has worked closely with the Thai government for several years to help them prepare to implement vaccine studies. Since 1995, this collaboration has involved a range of activities, including measuring the level of new infections in Thailand, identifying a group of individuals who are willing to participate in a trial and can be followed over time to evaluate risk behaviors and infection, and working with the community to build the understanding and support necessary to implement the trial. Second, CDC has and will continue to work with Thai health officials and VaxGen to ensure that individuals in the trial receive appropriate risk reduction counseling and are fully educated about how the trial works, the potential risks and benefits of participation, and the need for maintaining good behavioral risk reduction practices during the trial.

For example, as the trial proceeds, CDC will evaluate the impact of the trial on both participant and community attitudes and behaviors. This information will be critical not only to this community, but also to the future evaluation and implementation of vaccine strategies. CDC is not providing direct financial support for this trial but will provide logistical, laboratory and data analysis support throughout the trial. CDC hopes that this and other vaccine trials underway will identify an HIV vaccine to help end this epidemic. Until such a solution is available, we must continue to reinforce the already proven behavioral and biomedical methods of HIV prevention.

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta, GA 30333

February 9, 1999

Dear Colleague:

It is estimated that over 30 million individuals worldwide are infected with HIV – the vast majority of whom live in the developing world. One country in particular, Thailand, has experienced a rapidly escalating and severe HIV epidemic since 1988. Among the 60 million inhabitants of Thailand, as many as 800,000 are currently believed to be living with HIV.

Despite innovative and persistent prevention efforts, HIV continues to spread rapidly, particularly among Thailand's population of injection drug users (IDUs). Methadone treatment, education and counseling on HIV prevention, and easy access to sterile needles have certainly helped to slow the epidemic. Yet, among IDUs in Bangkok, 6% continue to become infected each year. In addition to being one of the nations most severely affected by HIV, Thailand has emerged as one of the nations most committed to ending its toll.

This week, Thailand became the first developing nation to announce a Phase III vaccine efficacy trial. As part of the Thailand National Plan for HIV Vaccine Research, the Bangkok Metropolitan Administration (BMA) is leading the three-year collaborative research trial to evaluate the ability of AIDSVAX to prevent HIV infection among uninfected IDUs in Bangkok. AIDSVAX was developed by VaxGen, a U.S. vaccine developer. BMA is conducting the trial in conjunction with VaxGen, the Mahidol University Faculty of Tropical Medicine in Bangkok, and the HIV/AIDS Collaboration (a longstanding research collaboration between the Thailand Ministry of Public Health and CDC).

The version of AIDSVAX to be tested in Thailand is designed to induce antibodies to HIV-1 subtypes B and E, the subtypes of HIV most common in Southeast Asia and the Pacific Rim. VaxGen is already evaluating another version of AIDSVAX designed to protect against strains common in North America. That trial began in June, 1998 and will include 5,000 volunteers in multiple sites throughout the United States. Early reports from several smaller trials of AIDSVAX in both Thailand and the United States have shown the vaccine to be safe and capable of inducing antibodies against these strains of HIV.

The Thailand trial will be conducted among uninfected IDUs attending 17 drug treatment clinics in Bangkok. The design is a randomized, double-blind, placebo-controlled trial in which half of the 2,500 volunteers receive the AIDSVAX vaccine and the other half receive placebo injections which do not include the vaccine. Neither the researchers nor the participants know which participants are in each half of the trial.

To guard against the relaxation of preventive behaviors, all volunteers receive extensive counseling on how to protect themselves against HIV infection, as well as explicit warnings that this vaccine may not protect them from infection. To further ensure that trial participants are not

inadvertently placed at any risk, the trial design, as well as all procedures and protocols for study recruitment and counseling, have received extensive scientific and ethical review by Institutional Review Boards and ethical committees of all involved agencies, both Thailand and U.S. governments, and the Joint United Nations Program on HIV/AIDS.

CDC's primary role in the Thailand trial is two-fold. First, continuing our longstanding research collaboration, CDC has worked closely with the Thai government for several years to help them prepare to implement vaccine studies. As the trial proceeds, CDC will continue to provide technical consultation as needed, as well as assistance with laboratory testing and processing, and analysis of results. Second, CDC is working with Thai health officials and VaxGen to ensure that individuals in the trial receive appropriate risk reduction counseling and are fully educated about how the trial works, the potential risks and benefits of participation, and the need for maintaining good behavioral risk reduction practices during the trial.

Vaccine trials in general, as well as overseas research, always present complex challenges. To outline important issues surrounding this and other vaccine studies, we have developed a fact sheet (attached) with more detailed information, as well as a document that answers questions that could arise. These documents are available on the Internet at http://www.cdc.gov/nchstp/hiv_aids/vaccine.htm .

CDC is very proud of our collaboration with Thailand. This collaboration has yielded vital research findings in the past -- findings that have had broad positive implications for the developing world. We hope that this vaccine -- along with other vaccine trials underway -- takes us a step closer to a time when HIV can be eliminated as a public health threat. Until that time, we must continue to reinforce the already proven behavioral and biomedical methods of HIV prevention.

As always, if you have any questions or comments, please feel free to call our Office of Communications at (4040 639-8890.

Sincerely,

Helene D. Gayle

Helene D. Gayle, M.D., M.P.H.
Director
National Center for HIV, STD, and TB Prevention
Centers for Disease Control and Prevention

cc: Dr. Tim Mastro, Bangkok
Dr. Kevin De Cock
Dr. Bill Heyward

FDA Allows Large-Scale Trial of AIDS Vaccine

By Ralph T. King Jr.
Staff Reporter of The Wall Street Journal

Virologist Donald Francis, who successfully battled Ebola in the Sudan and smallpox in India, is now taking on the trickiest assignment of his career: an international test of an AIDS vaccine.

Dr. Francis plans to announce today that his company, VaxGen Inc., has won

HEALTH

permission from the Food and Drug Administration to launch the nation's first large-scale test of a vaccine for AIDS prevention. The Phase III trial will include 5,000 volunteers in the U.S. and 2,500 in Thailand and take at least three years to complete.

"This is a watershed event in the AIDS crisis," says Seth Berkley, president of the nonprofit International AIDS Vaccine Initiative.

An effective AIDS vaccine in theory would train the human immune system to ward off infection by creating antibodies. But Dr. Francis's vaccine could turn out to be another false hope in the fight against AIDS, which afflicts 30 million people around the world. Some respected researchers have already dismissed Dr. Francis's vaccine—called Aidsvax—as ineffective. What is more, a growing body of research indicates that protective immunity against HIV, the elusive, unpredictable virus that causes AIDS, can't be won by a traditional vaccine alone.

In giving a green light to the trial of any vaccine, the FDA doesn't endorse the experimental approach or express an opinion on the likelihood of its success. Its chief criteria include safety and indications of biological activity from prior testing. Interim results from VaxGen's Phase I and II trials, in which some volunteers received placebos, showed that measurable antibodies were induced in more than 90% of those who received the vaccine, the company says.

Today's announcement, confirmed by the FDA, will mark the latest milestone in a long and visible quest by Dr. Francis. He was among the first to warn of the epidemic in the early 1980s, while working for the Centers for Disease Control, and was lionized in "And the Band Played On," the Randy Shilts book about the epidemic's early days. (Matthew Modine played Dr. Francis in the film version.) He subsequently went to work for **Genentech** Inc., where he helped develop an AIDS vaccine called gp120. Four years ago, after small-scale trials of gp120, the federal government denied funding for an expanded trial. There were doubts about the vaccine's effectiveness and fears that volunteers would become infected. Genentech, which had spent $50 million on gp120, shelved it. In 1996, Genentech spun off the gp120 group as VaxGen, retaining a 25% interest in the new company.

Elsewhere, vaccine development was slowing as attention shifted to successes in treating HIV with protease-inhibitor "cocktail" therapies. VaxGen pressed on, creating a new double-barreled version of gp120—Aidsvax—aimed at two of the most common strains of the virus found in the U.S., rather than one. To proceed, VaxGen raised $27.5 million from private investors and recruited clinics around the country to treat volunteers.

Donald Francis

Phase III trials are expected to begin in the U.S. this month and in Thailand by the end of the year. Phase I and II trials of Aidsvax are continuing.

Dr. Francis's doubters include David Baltimore, a Nobel Prize winner who heads a government advisory committee on AIDS vaccines and is president of the California Institute of Technology. "I personally believe people should be able to try what they want to try, but it's a very, very long shot to expect anything that's measurable," Dr. Baltimore says. He cites recent research, including Dr. Francis's Phase II trials of Aidsvax's predecessor in the early 1990s, indicating that antibodies induced by traditional protein vaccines—such as Aidsvax—are unlikely to protect against HIV.

Worse, Dr. Baltimore adds, the trial could "seriously dent the reservoir" of people willing to participate in future trials of AIDS vaccines that might be more promising than Aidsvax.

John Moore, an HIV researcher at the Aaron Diamond AIDS Research Center in New York, has studied the same research as Dr. Baltimore and is also skeptical. Like Dr. Baltimore, Dr. Moore believes that Aidsvax's effectiveness will be so low it will be hard to measure, invalidating its use. "It's going to achieve no practical benefit

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FDA Permits AIDS-Vaccine Test

Continued From Page B1

to the population," he says.

Researchers who believe that a traditional vaccine can't protect against AIDS by itself think it may also be necessary to boost the white blood cells known as killer T-cells for an all-out attack on HIV-infected cells. This combination approach is being tested by a unit of France's Rhone-Poulenc SA and Chiron Corp. but it won't be ready for the large-scale, final stage of clinical trials—Phase III—for at least another year.

A few other AIDS vaccines are currently in Phase I trials, But major drug makers aren't active in that field partly because the basic interaction between HIV and the immune system is still poorly understood. One exception: Merck & Co., which is in early stage development of a vaccine containing HIV genes instead of the whole virus.

Dr. Francis, a trim 57-year-old with unruly shocks of graying brown hair, shrugs off what he brands the "theoretical babbling" of his scientific critics. If the Phase III trials show his vaccine is even 50% effective, it could still drastically cut the advance of AIDS, he says. He recalls that Jonas Salk's 70%-effective polio vaccine spared hundreds of thousands of children before a superior vaccine, made by Albert Sabin, was available seven years later.

"I applaud debate but not if it impedes progress. We've reached the limit of basic research, and now it's time to move forward," Dr. Francis says.

There is evidence that the second generation of Dr. Francis's vaccine is improved. The original version induced antibodies for only the most common strain of virus found in the U.S., providing questionable benefit for patients with up to six other known strains world-wide. Patients in the vaccine's earlier trials who became infected had one of these less common strains, Dr. Francis says.

The new "bivalent" version for U.S. patients offers broader coverage, says Dr. Francis. The vaccine to be used in Thailand was developed from two strains prevalent in that country. So far, more than 200 people have been injected with either of the bivalent forms of Aidsvax, including Dr. Francis himself.

Anthony Fauci, head of the National Institute for Allergy and Infectious Diseases and the man most responsible for killing Dr. Francis's vaccine four years ago, has reviewed data from Dr. Francis describing the bivalent design and calls it "interesting." Dr. Fauci says he doesn't regret the 1994 decision but thinks this trial could prove worthwhile. "If they have the resources to do it, there's a possibility that something can be learned," he says.

For Dr. Francis, who has little business experience, a nerve-racking question was whether he could attract sufficient capital to revive his vaccine. In early 1997, he and Robert Nowinski, VaxGen's co-founder and chairman, took their story on the road. Dr. Nowinski plumbed his contacts in the Seattle area, where he had previously founded three biotechnology companies. In less than five months, several hundred investors provided the necessary funds.

VaxGen

Tuesday, June 2, 1998

Dear Colleague:

VaxGen, Inc. anticipates announcing a significant step in our vaccine development. We believe this announcement will garner the attention of the media, and that, because of the role you have played in combating this epidemic, you may be called upon for comment on this event. We therefore are sending along to you the same information we have provided or will be providing to the members of the media, as well as additional scientific materials.

We hope this information will be of help to you in any dealings you may have with the media, and also in understanding how VaxGen perceives its mission and goals. We are sending these materials along for informational purposes only, without expectations as to your cooperation with the media or the viewpoints that you may choose to express.

Our communications counsel, Sitrick And Company, is serving as our liaison with the media and the public. Please feel free to contact Donna Walters or Nicole Lynch at (310) 788-2850 if they can provide you with any assistance in these matters. Sitrick And Company will fax our press release to you when it is issued. You may also check our web site, at www.vaxgen.com/ for press releases and other information.

Sincerely,

Donald Francis

Donald P. Francis,
President

501 Forbes Boulevard, South San Francisco, CA 94080 (650) 225-7000 FAX: (650) 225-7057

VaxGen

A VACCINE FOR HIV
BACKGROUND ON VAXGEN AND ITS AIDSVAX VACCINE

VaxGen is a South San Francisco, Calif.-based company that has taken on one of the world's most urgent public health issues: preventing the spread of the deadly HIV (Human Immunodeficiency Virus), the cause of AIDS. Led by some of the country's most noted specialists in AIDS, vaccines and virology, VaxGen anticipates moving its AIDSVAX vaccine into Phase III clinical trials in North America in the summer of 1998 and in Thailand by the fall of 1998. The vaccine to be tested is designed, in one formulation, to protect against the strains of HIV typical of the AIDS-causing virus found in the Americas, Western Europe and Australia and, in a separate formulation, against the strain typical of the AIDS-causing virus in Thailand, Japan, Korea, Taiwan and Indonesia.

This is the story of how and why AIDSVAX was developed.

THE TERRIBLE COST OF HIV AND AIDS

The Names Project "AIDS Quilt" covers 16 football fields. Yet, if all those who have died so far from AIDS were named on the quilt, it would cover more than 2,400 football fields.

In terms of human suffering, the tragic cost of HIV and AIDS can never be measured. But the statistics of the epidemic give us the outline.

AIDS has already claimed nearly 12 million lives and another 30 million individuals are infected with HIV. Each and every day, another 16,000 to 17,000 individuals, worldwide, become infected. AIDS has already orphaned more than 8 million children around the world, according to the December 1997 Report on the Global HIV/AIDS Epidemic by UNAIDS and the World Health Organization.

By the year 2000, it is estimated that 50 million individuals will be infected with HIV and, by 2010, the death toll could climb to 40 million. Even with today's advances in research and treatment, diagnosis of HIV infection in most parts of the world is still a death sentence.

Not since the Black Death killed more than one-quarter of Europe's population in the 14th Century has a single disease so threatened human life. The last worldwide public health tragedy, the "Spanish" Influenza epidemic, claimed 20 million lives in 1918-1920 — years before the electron microscope helped scientists identify and combat viruses.

More than $1 billion is spent each year looking for a cure. Meanwhile, the United States spends an estimated $15 billion a year to care for persons with AIDS; total cost for AIDS patients' medical care, including drug therapies intended to delay the onset of AIDS in HIV-infected individuals, is far in excess of $200,000 per person.

501 Forbes Boulevard, South San Francisco, CA 94080 (650) 225-7000 FAX: (650) 225-7057

In developing countries where the HIV infection rate has been soaring, the cost of palliative care of HIV-infected individuals and AIDS patients far outstrips the total amount the governments of those countries are able to spend on their nation's general health care.

PREVENTION: THE ONLY EFFECTIVE WAY TO END THE AIDS EPIDEMIC

"We'll never end this epidemic unless we have a vaccine."
— Sandra Thurman, chair of the White House Office of National AIDS Policy.

In any epidemic, two very crucial needs compete for limited resources: caring for those already suffering and preventing further spread of the disease. Dr. Donald P. Francis, a physician, public health official, virologist and one of the founders of VaxGen, has confronted this dilemma throughout his career, most particularly while fighting cholera and Ebola epidemics in Africa, and smallpox and tetanus epidemics in India.

Dr. Francis's responsibilities in those crisis often entailed staying a jump ahead of the epidemic, so that the uninfected in the next village might be vaccinated. In doing so, he helped eradicate the infections and spare additional thousands suffering and possible death.

Throughout his years as a physician, Dr. Francis has been a first-hand witness to the power of vaccines. A protégé of Jonas Salk (who developed the first polio vaccine) and a clinical scientist early in the development of the Hepatitis B vaccine, Dr. Francis had long been waging clinical war on viruses when the most deadly of modern viruses, HIV, began cutting its terrible swath through the young homosexual male population of America.

Working as director of AIDS laboratory at the federal Centers for Disease Control in the early 1980's, Dr. Francis was deeply involved in the scientific quest to find the organism that causes AIDS. In the years that followed, he continued his work in AIDS, staying in the forefront of the efforts to develop a public health response to the crisis.

Early in the crisis, scientists and physicians like Dr. Francis struggled with limited resources to identify the disease, deal with its terrible consequences, and begin the search for treatments and cures. Meanwhile, the virus continued its ferocious spread — checked only as public education increased. And while the rate of new HIV infections in the developed world has been slowed, it is far from being stopped and, indeed, remains one of the leading causes of death among young men and women.

The rate of infection continues to rise in many regions of the world, especially among populations out of the reach of the mass media or for whom sociological, religious or financial reasons make precautionary measures impractical. And as the virus spreads, it has spared no group, no race, no gender, and now infants, adolescents and heterosexual women are among the groups most at risk of infection.

A report of the Rockefeller Foundation-sponsored meeting of international AIDS and HIV experts held in 1994 stated: "The HIV epidemic continues to spread throughout the world despite current prevention efforts. The development and distribution of a safe, effective and inexpensive preventive HIV vaccine currently represents the best hope for controlling the global HIV/AIDS pandemic."

Since then, an estimated 16 million more people have become infected with HIV.

THE MISSION: DEVELOP A VACCINE AGAINST HIV

"I can't imagine our making a vaccine without a very close partnership with industry."
— Anthony Fauci, director, National Institute of Allergy and Infectious Diseases

Dr. Francis' work in the AIDS and HIV crisis dominated the last 11 years of his 21-year career at the CDC. After scientists at the Institut Pasteur identified HIV, he worked closely with the French researchers to prove that HIV was indeed the agent that caused AIDS. Dr. Francis was one of the first doctors to sound an early warning that the nation's blood supply could be at risk from HIV, and pressed for a rational public policy to deal with the AIDS crisis. His work with the CDC brought him back to his native California, where he served as AIDS Advisor to the State of California and worked with pharmaceutical companies to begin their own HIV vaccine research.

From 1988 to 1992, Dr. Francis was Special Consultant on AIDS to then-San Francisco Mayor Art Agnos, and chair of the mayor's HIV Task Force.

After retiring from the CDC, his commitment to finding a vaccine for HIV led him to join Genentech, Inc. in South San Francisco, the leader among companies then doing research on potential HIV vaccines. Beginning in 1993, he worked with Dr. Phillip Berman, who had been directing that company's scientific efforts to develop an HIV vaccine. The vaccine developed by Dr. Berman's team — the forerunner of today's AIDSVAX — had already been shown to neutralize the laboratory strain of HIV, and to protect chimpanzees from HIV infection. Clinical testing of this vaccine had already begun, under the auspices of the National Institutes of Health. With further study, the vaccine was shown to be safe for use in humans and to induce immunological responses in humans. It needed to be tested in large-scale studies to determine its efficacy.

In June of 1994, NIH's AIDS Research Advisory Committee, going against the recommendation of NIH's own expert vaccine committee, decided not to fund expanded and more expensive clinical trials of two vaccines — those developed by Genentech and Chiron, another California biotech company involved in HIV vaccine research.

The wisdom of that decision and the politics surrounding it are still subjects of a heated debate among scientists actively pursuing an HIV vaccine. Experts, including a panel brought together by the World Health Organization's AIDS committee (the forerunner of UNAIDS), who reviewed the data from the initial clinical trials have supported moving these vaccines ahead into wide-scale clinical testing.

Within two years, the ramifications of the NIH decision were clear: Private industry in the United States began curtailing efforts in HIV vaccine research and the Vaccine Research and Development Area Review Panel said NIH's own vaccine development programs were "in crisis."

Genentech had spent more than $50 million and 10 years on its HIV vaccine research. In 1995, when that company's business plan diverted it from all vaccine research, the commitment of Drs. Francis, Berman and other HIV vaccine researchers at Genentech remained strong.

It was then that Dr. Francis teamed up with fellow virologist Dr. Robert Nowinski, a Seattle entrepreneur who already had established three publicly held biotechnology companies, to spin the HIV vaccine unit out of Genentech. Together, they founded VaxGen and set about to raise financing so that the fledgling company could continue the research on AIDSVAX and fund clinical trials of the vaccine.

The work of the VaxGen team has led to refined and enhanced formulations of the original Genentech vaccines so that today there are two "bivalent" AIDSVAX formulations, each designed to protect against the major strains of HIV. The formulation that will be used in clinical trials in North America is designed to protect against the strains typical of the virus found in the Americas, Western Europe and Australia. The formulation to be used in the Thailand trials is designed to protect against the strains typical in Thailand, Korea, Japan, Indonesia and Taiwan. In Thailand alone, approximately 1 million people — 2% of that country's population — are already infected with HIV.

In early 1998, VaxGen began testing its new, bivalent forms of AIDSVAX in Phase I/II confirmatory trials — clinical studies designed to test whether the current forms of the vaccine, like the original "monovalent" forms, are safe for use in humans and whether they produce a strong immune response. Indeed, those studies have demonstrated that these second-generation vaccines induce potent antibodies to the two major varieties of the virus targeted by each formulation.

These studies followed yet earlier trials of monovalent AIDSVAX. So far, more than 1,200 persons have been inoculated with monovalent and bivalent AIDSVAX through clinical trials in the United States and Thailand. The vaccine induces antibodies in more than 99 percent of inoculated individuals, without adverse side effects, other than an occasional sore arm at the injection site.

Like all other vaccines, AIDSVAX is designed to train the human body's immune system — by creating antibodies — to protect itself against infection by the virus, if and when it ever encounters it. Specifically, the vaccine uses a genetically engineered protein from the surface of the virus. Injecting this recombinant protein stimulates production of antibodies that would attack any future invading HIV, thus preventing the virus from binding to, and infecting, healthy T-cells.

Now, VaxGen is preparing to take the vaccine into Phase III clinical trials, to study the efficacy of AIDSVAX in preventing infection by HIV. These trials would involve 5,000 volunteers in the United States, and 2,500 in Thailand.

THE SCIENTIFIC DEBATE

"... It is no longer a question of whether we can develop an AIDS vaccine, it is simply a question of when. And it cannot come a day too soon."
— President Clinton, May 18, 1997

In May of 1997, speaking to an audience at Morgan State University in Baltimore, Md., President Clinton called for a national commitment "to developing an AIDS vaccine within the next decade" and called on the pharmaceutical industry and other nations of the world to join the resolve. "Only a truly effective, preventive HIV vaccine can limit and eventually eliminate the threat of AIDS," he said.

The only way to reach that goal is by moving scientific research from the laboratory into human clinical trials. In the United States, any new medicine — and that includes preventive medicines like vaccines — must be tested through a three-phase process, stringently reviewed and independently monitored by the Food and Drug Administration.

"We ... need to go ahead with wide-scale testing and be willing to fail," said Dr. Richard Marlink, executive director of the Harvard AIDS Institute in 1997. "We're not going to succeed if we're not willing to fail."

Simply put, a vaccine **must** be tested to determine whether, and how well, it works.

But controversy and debate over the state of scientific knowledge and procedures have surrounded this phase of the AIDS crisis, just as they have marked each new step in the identification and treatment of this terrible disease.

While such controversies have impeded the rapid development of an HIV vaccine, they are not unique to this crisis. Science, in fact, seems to thrive on debate and it relies on questions, trial-and-error and differences in approach to move our knowledge forward. If nothing else, the history of polio vaccines teaches this lesson quite well. Many scientists criticized — even laughed at — Jonas Salk's approach to a polio vaccine, and supported a different approach being worked on by Albert Sabin, which they believed would be more effective. Salk, meanwhile, went on to develop and test his vaccine.

Salk's vaccine was tested in 450,000 children, found to be 70% effective in protecting those who were vaccinated from polio, approved in 1955 and administered to thousands upon thousands of children — sparing untold thousands from the crippling disease — in the seven years that passed before Sabin's vaccine was ready.

The formidable challenges presented by AIDS and HIV, including the way HIV attacks the immune system and the number of HIV strains, have generated a wide array of scientific theories about and approaches to development of a vaccine. Some scientists insist that before an effective HIV vaccine can be developed, we must understand more about the human immune system. Some scientists insist that to be effective, an HIV vaccine must provide cellular immunity.

Despite this heated debate, VaxGen has continued to move AIDSVAX forward through the testing and regulatory process. Because of its commitment and persistence, VaxGen is now poised to become the first company to test an HIV vaccine in wide-scale human clinical trials.

And now, just as VaxGen and AIDSVAX are at the forefront of HIV vaccine development, HIV and AIDS scientists, physicians and public health officials are increasingly recognizing that an HIV vaccine is needed so urgently that the world cannot wait for all science's questions to be answered before clinical trials are done.

THE CALL HAS GONE OUT. VAXGEN IS READY

"On one point everyone agrees: In order to achieve our overall objective ... Phase III clinical trials must be done."
— Saladin Osmanov of UNAIDS

The March 18, 1998 report of the Presidential Advisory Council on HIV/AIDS, entitled "Achieving the Goal of an AIDS Vaccine," stated: "With the gravity of the current AIDS pandemic in the world, and the need to proceed with vaccine development as quickly as possible, the Council acknowledges that it will be necessary to test various traditional and novel vaccine design strategies in human clinical trials, even before the scientific correlates of protection have been fully deciphered. We thus advocate the simultaneous implementation of both basic and

empiric scientific approaches. These parallel approaches should be recognized within the comprehensive Federal plan for AIDS vaccine development."

When VaxGen begins Phase III testing of AIDSVAX this year, 17 years after the epidemic began, it will mark a new era in the crisis as scientists begin to deal with preventing AIDS. It could well be the beginning of the end.

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Additional information is available on our website at:
http://www.vaxgen.com/

VaxGen

ABSTRACT
OF PAPER TO BE PRESENTED BY DR. DONALD P. FRANCIS AT XII INTERNATIONAL CONFERENCE ON AIDS GENEVA, SWITZERLAND JUNE, 1998

AIDSVAX B/B and AIDSVAX B/E. Likely to protect. But how well and for how long must await results of planned efficacy trials.

Background: The safety and immunogenicity of AIDSVAX has been evaluated through administration of monovalent subtype B formulations (MN and IIIB) to over 1,000 humans. Potential human efficacy is reflected by its ability to protect chimpanzees from high-dose challenge. To maximize the potential efficacy, geography-specific formulations to cover different HIV-1 subtypes need to be produced for efficacy testing.
Methods: We reviewed all human and chimpanzee data regarding the safety, immunogenicity, and potential efficacy of AIDSVAX. In addition, we examined viruses infecting vaccinated humans ("breakthroughs"). With this information, a second geography-specific antigen was selected, produced, and combined with MN and administered to humans in the United States and in Thailand using bivalent formulations — B/B for the U.S. (120 volunteers) and B/E for Thailand (90 volunteers). To test the efficacy of these bivalent vaccines we designed Phase III trials.
Results: Minimal injection site reactions are the only associated adverse reactions observed. Data from the bivalent studies are pending. Monovalent formulations induce humoral immune responses in 99.5% of recipients. These occur after two initial doses give at T-0 and T-1 month but the tiers of anti-gp120, anti-V-3, CD4 blocking and neutralizing antibodies are increased with booster doses given at T-6 months and T-12 months. Lymphocyte transformation and positive skin tests to rgp120 are common. Results from testing sera following B/B and B/E vaccination suggest the addition of macrophage-tropic strains with neutralizing sites complementary to MN will increase the likelihood of protection. Plans for U.S. and Thai Phase III trials have been accepted by the U.S. FDA.

Conclusion: Indications are that AIDSVAX is safe and will likely protect humans from HIV-1 infection. The addition of complementary macrophage-tropic strains to the monovalent MN vaccine are expected to increase the likelihood of protection — the extent of protection will await the results of planned efficacy trials.

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ABSTRACT
OF PAPER TO BE PRESENTED BY DR. PHILLIP W. BERMAN
AT XII INTERNATIONAL CONFERENCE ON AIDS
GENEVA, SWITZERLAND
JUNE, 1998

Neutralization of macrophage tropic and T cell line tropic viruses by a bivalent subtype B/E vaccine designed for Asia.

Background: Genetic analysis has shown that the majority of HIV-1 infections in the U.S.A. and Western Europe are due to subtype B viruses, whereas in parts of Asia (e.g. Thailand) both subtype B and subtype E viruses are in circulation. In this report, a bivalent subunit vaccine designed to provide protective immunity against infection by subtype B and subtype E strains of HIV-1 was evaluated in preclinical immunogenicity studies.
Methods: Recombinant gp120 was prepared from a prototypic subtype B virus ($HIV\text{-}1_{MN}$), representative of viruses circulating in the U.S.A. and Western Europe, and a prototypic subtype E virus ($HIV\text{-}1_{CM244}$), representative of viruses circulating in Thailand. Rabbits were immunized with these antigens alone and in combination. The resulting antisera were evaluated for gp120 binding, reactivity to V3 domain peptides, and for neutralization of CXCR4 and CXCR5 dependent virus isolates from the United States and Thailand.
Results: Studies with monovalent formulations showed that the immune responses to both antigens were highly cross-reactive and sometimes elicited antibodies capable of inter-subtype virus neutralization. Antibodies to the bivalent formulation neutralized viruses possessing a variety of diverse phenotypes, including syncytia inducing (SI) and non-syncytia inducing (NSI) primary isolates; viruses using either the CCKR5 or CXCR4 chemokine receptors, viruses differing in their sensitivity to soluble CD4.

Conclusion: Recombinant gp120s prepared from subtype B and subtype E viruses elicit antibodies able to neutralize both macrophage tropic and T cell line tropic viruses. Combining antigens representing two distinct genetic subtypes increased the potency and reproducibility of the inter-subtype virus neutralizing antibody response.

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SUMMARY OF VAXGEN'S PLANNED PHASE III TRIALS OF AIDSVAX

Location	North America	Thailand
Vaccine	AIDSVAX B/B	AIDSVAX B/E
Sites	30-40	16
Volunteers	MSM & High-Risk Heterosexuals	Injection Drug Users
Number	5,000	2,500
Start	Summer 1998	Fall 1998 (official approval)
Length	3 years	3 years
Endpoints	Infection & Viral Load	Infection & Viral Load

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VAXGEN, INC. — THE DEVELOPER OF AIDSVAX

VaxGen, Inc. was formed in 1995 to develop and market an HIV vaccine. The co-founders of the firm are Dr. Donald P. Francis, its President, and Dr. Robert Nowinski, its Chairman — both retrovirologists with extensive backgrounds in HIV research.

VaxGen continues essential research begun at Genentech, Inc., in 1984, where Dr. Phillip Berman, now VaxGen's Vice President of Research, directed Genentech's HIV vaccine research team.

VaxGen's ongoing research has led to the development of AIDSVAX, a vaccine designed to provide protection against the major strains of HIV in the Americas, Western Europe and Southeast Asia. Two formulations of the new bivalent AIDSVAX have been studied in Phase I/II confirmatory trials at multiple sites in the United States and Thailand. The company anticipates commencing Phase III trials of AIDSVAX in North America and Thailand during 1998, under the direction of Dr. Nzeera Virani-Ketter, VaxGen's Senior Director of Medical Affairs.

VaxGen is a privately held company, based in South San Francisco, Calif., with 25 employees. Serving on its board of directors are Drs. Francis, Nowinski and Berman; Randall Caudill, President of Dunsford Hill Capital Partners, a San Francisco-based financial consulting firm; Stephen C. Francis, Co-founder and Vice Chairman of Fischer, Francis, Trees and Watts, a worldwide manager of fixed-income portfolios; Daniel T. Reiner, a founder and former Chief Executive of several high-technology and manufacturing companies; and William D. Young, Chief Operating Officer of Genentech.

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Additional information on VaxGen and AIDSVAX is available on our website at: http://www.vaxgen.com/

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VAXGEN AND AIDSVAX
A CHRONOLOGY

1981	Dr. Donald Francis, working at the Centers for Disease Control, begins his research on AIDS.
1981	Dr. Robert Nowinski founds Genetic Systems Corp., the manufacturer of one of the world's first HIV diagnostic blood-screening tests.
1983	HIV is discovered as the cause of AIDS.
1984	A research team at Genentech, Inc., with Dr. Phillip Berman as its leader, begins research on an HIV vaccine that is the foundation for the current AIDSVAX vaccines.
1985	Research at Genentech, based on gp120, leads to development of a vaccine that produces neutralizing antibody to HIV in laboratory animals.
1990	Studies conducted by the Genentech team show that the vaccine protects chimpanzees against HIV infection.
March 1992	Phase I trials of monovalent gp120 vaccine begin; trials show that the vaccine is safe for use in humans.
December 1992	Phase II trials of monovalent gp120 vaccine begin; trials show that the vaccine is safe and induces an immunological response in humans.
1995	VaxGen is founded as Drs. Francis and Nowinski spin off the HIV vaccine unit of Genentech, Inc.
1997	VaxGen's team, led by Dr. Berman, develops two bivalent formulations of its AIDSVAX vaccine, designed to protect against the two major strains of HIV found in the Americas, Europe and Asia.
May 1998	VaxGen confirms immunogenicity and safety of AIDSVAX in Phase I/II trial at multiple sites.

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DONALD P. FRANCIS
PRESIDENT, CO-FOUNDER

Dr. Donald P. Francis, President and Co-founder of VaxGen, Inc., has been in the front lines of the battle against AIDS since 1981 and was one of the first scientists to suggest that the then-mysterious disease was caused by an infectious agent.

Throughout his professional life, his passion in fighting the spread of infectious diseases took him from India to Africa, and from Atlanta to San Francisco during a 21-year career with the U.S. Centers for Disease Control.

As a young CDC doctor working with the World Health Organization during the early 1970s, Dr. Francis played a key role in eradicating smallpox from regions of India, Bangladesh, Sudan and the former Yugoslavia, a population of more than 240 million.

In 1970, he battled the cholera epidemic in Nigeria and in 1976, he fought the Ebola virus in Sudan during what was the first outbreak of that deadly disease.

Dr. Francis' current efforts to develop a vaccine to prevent the spread of AIDS rests on the foundation laid in his earlier work in the successful development of a Hepatitis B vaccine, and his doctoral work on feline leukemia virus. (Much like HIV in humans, the feline leukemia virus develops slowly in feline hosts, which display no outward signs of infection as the virus destroys their immune systems.)

Dr. Francis was assigned by the CDC to conduct clinical trials testing the Hepatitis B vaccine in a volunteer group of gay males, the highest risk group for Hepatitis B. He was one of two principal investigators who conducted Phase III clinical trials for the Hepatitis B vaccine, which resulted in the first licensing of that vaccine in the early 1980's. As the AIDS epidemic surfaced, he was called to Atlanta to head activities of the CDC's AIDS Laboratory.

He was one of the first scientists to grasp the significance of the AIDS epidemic and to realize the impact it would have on the United States. Always outspoken, he has been an indefatigable advocate for a swift and logical public health response.

Dr. Francis was director of the CDC's AIDS lab during the scientific quest to find the organism that causes AIDS in the early 1980s. After the Institut Pasteur identified HIV, he worked closely with the French researchers to prove that HIV was indeed the agent that caused AIDS. He was one of the first doctors to sound an early warning that the nation's blood supply could be at risk from HIV.

Dr. Francis' efforts to call attention to the threat of AIDS and warn of the inadequacy of the public health response were chronicled in *And the Band Played On,* journalist Randy Shilts' seminal account of the early years of the AIDS epidemic.

From 1985 to 1992, Dr. Francis served as the Centers for Disease Control's AIDS Advisor to the State of California. From 1988 to 1992, he also served as Special Consultant on AIDS to then-San Francisco Mayor Art Agnos, and chair of the mayor's HIV Task Force.

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He retired from the CDC in 1992 and began work with Genentech, Inc., of South San Francisco, in 1993. Genentech had made significant breakthroughs in research towards a vaccine against AIDS, including development of a vaccine shown to protect chimpanzees against HIV infection.

In 1995, Dr. Francis and fellow retrovirologist Dr. Robert Nowinski guided the spin-off of Genentech's HIV vaccine unit and founded VaxGen to continue the vital work as an independent company.

A third-generation California physician, Francis did his undergraduate studies at the University of California at Berkeley. He received his M.D. from Northwestern University and his Doctor of Science in Virology from Harvard. He did his internship and residency in pediatrics at the University of Southern California Medical Center in Los Angeles and his fellowship in infectious diseases at Harvard.

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VaxGen

ROBERT C. NOWINSKI
CHAIRMAN, CO-FOUNDER

Dr. Robert C. Nowinski, Chairman and Co-founder of VaxGen, Inc., is a scientist and entrepreneur whose 30-year career in science has been devoted to the study of retroviruses, the viruses that include HIV. As a businessman, he has been a pioneer in the biotechnology industry, having established three publicly held companies during the past 17 years.

Dr. Nowinski was a professor of microbiology and immunology at the University of Washington and served as head of the Virology Program at the Fred Hutchinson Cancer Research Center in Seattle.

In 1981, Dr. Nowinski founded Genetic Systems Corp., a publicly held biotechnology company, based in Seattle, where he served as Chairman and Chief Executive. Genetic Systems focused on diagnostics and the treatment of infectious diseases and cancer, and developed one of the first tests for HIV in collaboration with Institut Pasteur in France. It also developed a rapid test for chlamydia, a common genital infection, that resulted in a 100-fold expansion of testing for that disease.

Dr. Nowinski negotiated the merger of Genetic Systems into Bristol Myers Co. in 1986, and served as Vice President of New Technology for Bristol Myers until 1989.

He then founded ICOS Corp., a publicly held biotechnology company with a focus on treatment of inflammatory diseases. From 1989 through 1991, he held the positions of Chief Executive Officer and President of ICOS.

In 1992, Dr. Nowinski founded PathoGenesis Corp., another publicly held biotechnology company, which concentrated on developing therapeutic drugs for the treatment of such diseases as cystic fibrosis, multiple sclerosis and tuberculosis. He served as Chairman of that company until 1995. While serving as Chairman, Dr. Nowinski remained active in the research programs of the company and was one of the team leaders involved in identifying the viral cause of multiple sclerosis, for which he is a co-inventor on a patent application.

In 1995, he joined Dr. Donald P. Francis in founding VaxGen. Dr. Nowinski, with the role of directing the company's finance, was instrumental in raising capital funding for VaxGen, a spin-off of Genentech, Inc.

A native of New York, Dr. Nowinski received his undergraduate degree in 1967 from Beloit College in Wisconsin and his Ph.D. in immunology from Cornell University, Sloan-Kettering Division in New York City, in 1971.

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PHILLIP W. BERMAN
VICE PRESIDENT OF RESEARCH

Dr. Phillip Berman, Vice President of Research at VaxGen, has played a pivotal role in the quest for an AIDS vaccine during the past 14 years.

He was a principal scientist on the research team at Genentech, Inc., in South San Francisco, that, during the early 1980s, produced recombinant gp120 protein and showed that antibody to gp120 could neutralize HIV-1.

A major breakthrough for Dr. Berman and the Genentech team came in 1990 with the development of a vaccine that was able to protect chimpanzees from HIV infection.

While at Genentech, Dr. Berman and his team, using the gp120 model, conducted molecular epidemiological studies and selected new antigens to complement earlier vaccine preparations and to expand the breadth of protective immunity that could be achieved with the VaxGen AIDS vaccine.

Dr. Berman joined VaxGen in 1997, after the company was spun-off from Genentech, and has continued to lead VaxGen's HIV vaccine research. This research has led to the development of AIDSVAX, a bivalent vaccine designed to attack both the laboratory strain of HIV and strains typical of HIV infections in the Americas, Western Europe, the Caribbean and South Asia.

He has published more than 85 scientific articles and holds multiple patents in vaccines and recombinant DNA technology.

He began his postdoctoral career in 1977 doing research in autoimmunity and neurobiology at the Salk Institute in La Jolla, Ca. In 1981, when scientists announced the first breakthrough in the development of recombinant DNA, he moved to the San Francisco Bay Area to pursue this new field at the University of California, San Francisco.

Dr. Berman worked with Dr. Herbert Boyer from 1981-82 on projects relating to the expression of recombinant proteins within E. Coli bacteria.

He joined Genentech, the firm founded by Dr. Boyer, in 1982 and rose to the position of Staff Scientist. Dr. Berman held positions in both the Research and Process Sciences Divisions of Genentech. During his time there, he worked on a vaccine to prevent Herpes Simplex Virus infections, drugs to treat inflammation, and developed technology to improve the production of recombinant proteins.

He is a native of Los Angeles and earned his undergraduate degree from the University of California, Berkeley, and his Ph.D. in Biochemistry at Dartmouth Medical School in New Hampshire.

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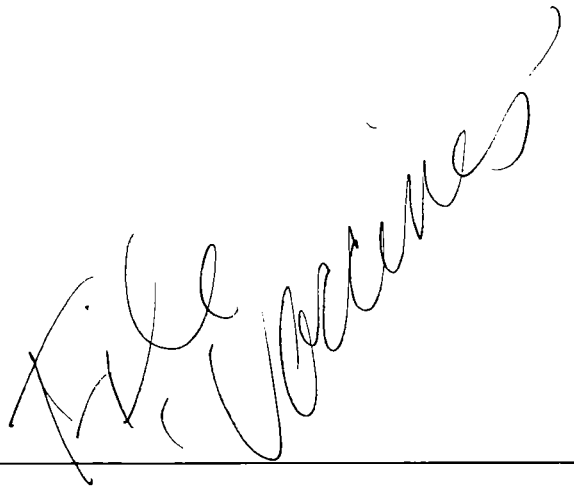

VIA FAX

TO: DR. SANDRA THURMAN

FROM: VaxGen Inc.

ATTN:

TO: FAX PHONE#: 2024562439

Job Number: 46125903-010-149-0021
TIME: Thu Aug 20 09:15:10 1998

4 pages including cover sheet

VaxGen

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For Immediate Release

W. Hollywood Clinic Begins Inoculations in Phase III Trial of AIDSVAX

South San Francisco, CA — August 20, 1998 — The AIDS ReSEARCH Center in West Hollywood, Ca., today will begin inoculating volunteers in the North American trial of AIDSVAX, the first-ever vaccine against HIV to be tested in Phase III human clinical trials. The clinic is the fifth to participate in the trial sponsored by VaxGen, Inc., the developer of AIDSVAX.

The North American Phase III trial got under way in June in Philadelphia and since then, clinics in St. Louis, Washington D.C. and Denver have been accepting volunteers. The trial is projected to expand to 30 to 40 clinics and 5,000 volunteers at risk for HIV infection.

"We are proud to be participating in this study because we are committed to the effort to prevent HIV infection," said Dr. Stephen Brown, Director of the AIDS ReSEARCH Center. "While we must, as a society, continue to explore treatments for those already infected and those suffering from AIDS, we know the only way to end this epidemic is to prevent new infections with a vaccine."

AIDSVAX has already been given to more than 1,200 individuals in earlier-stage trials. In June, the U.S. Food and Drug Administration cleared VaxGen to proceed with Phase III trials, which are designed to test the vaccine's efficacy.

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In Denver, the vaccine clinic at the Denver Department of Public Health began injecting volunteers in the Phase III trial on Wednesday, August 19, under the direction of Dr. Franklyn Judson, M.D., Director of Denver's Public Health Department and also Protocol Chairman for the VaxGen study.

"We are pleased to have the West Hollywood and Denver clinics join the AIDSVAX study," said Dr. Donald P. Francis, President of VaxGen. "Both these communities have been deeply affected by and involved with the AIDS crisis and these clinics are showing their continuing commitment to preventive research. The support of the volunteers, researchers and clinics is essential to VaxGen's goal of developing a vaccine against HIV."

Trial participants are selected from among volunteers who are at risk for HIV infection but who are currently uninfected. Over the course of 30 months, volunteers will be given seven injections, but neither volunteers nor researchers will know which volunteers are given the vaccine and which receive an inactive placebo.

In the North American trial, the volunteers will be selected from among individuals at risk through sexual transmission — primarily gay males and women with HIV-positive partners.

VaxGen anticipates beginning the Phase III trial of a separate formulation of AIDSVAX in Thailand later this year, following approval by the Thai Ministry of Health. That trial will involve 2,500 volunteers at risk of HIV infection through injection-drug usage.

Throughout the three-year trials, volunteers will be counseled on methods to avoid HIV infection and cautioned not to construe their participation in the trial as protection against infection. Follow-up with volunteers will continue for at least six months after the last injection is administered.

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At the end of the trial, the rate of infections in the group that received the placebo will be compared to the rate of infections, if any, among volunteers who received the vaccine. That comparison will be used to determine the efficacy of the vaccine.

Phase III trials are a critical step in the strictly regulated and monitored process by which a new vaccine or drug is tested and precedes application to the FDA to license and market the product.

Each AIDSVAX formulation is bivalent — that is, created from recombinant copies of the gp120 protein from the surface of two types of HIV. The vaccine to be used in test sites across North America is formulated to protect against infection by the major types of HIV-1 virus most typical of infections in the Americas, Western Europe and Australia. The formulation of the vaccine to be used in the Thai trial is designed to protect against the major types of the virus typical of infections in Southeast Asia and the Pacific Rim.

Earlier clinical trials have shown that AIDSVAX is safe for use in humans and induces a strong immune response. AIDSVAX cannot cause HIV infection or AIDS.

On August 18, VaxGen and the National Institute of Allergy and Infectious Diseases, an agency within the National Institutes of Health, announced that the NIAID will collaborate in research in conjunction with the Phase III trials of AIDSVAX.

VaxGen, based in South San Francisco, Ca., is a biotechnology company committed to making an HIV vaccine for worldwide use.

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Additional information is available on our web site at:
http://www.vaxgen.com/

Note: For information about volunteering in the West Hollywood study, phone: 310-358-2430