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National Institute of Allergy and Infectious Diseases <<http://www.niaid.nih.gov>>

NIH NEWS RELEASE

Wednesday, November 20, 2002

MAJOR HERPES VACCINE TRIAL LAUNCHED IN WOMEN

A pivotal efficacy trial of an experimental vaccine designed to prevent genital herpes in women began enrolling volunteers this week. The study will determine the vaccine's ability to prevent genital herpes disease in women who are free of two common types of herpes simplex viruses (HSV): HSV-1 and HSV-2. The trial will eventually enroll 7,550 women in at least 16 sites in the United States. It is the result of a partnership between the National Institute of Allergy and Infectious Diseases (NIAID) and the vaccine's manufacturer, GlaxoSmithKline Biologicals (GSK), headquartered in Belgium.

"This vaccine trial is an excellent example of a mutually beneficial collaboration between the public and private sectors," says NIAID Director Anthony S. Fauci, M.D. "More than one million new cases of genital herpes are diagnosed in the United States each year. The physical and psychological toll taken by this sexually transmitted disease is considerable. Successful public-private collaborations such as this one will take us closer to our goal of reducing the spread of genital herpes."

Previous efficacy trials of the GSK vaccine were conducted in smaller numbers of men and women who did not have genital herpes but whose sexual partners were known to be infected. For reasons still not well understood, the vaccine prevented herpes disease in more than 70 percent of HSV-1 and HSV-2 negative women but had no clear effect in men. The results of these earlier Phase III trials are reported in this week's edition of "The New England Journal of Medicine".

Finding thousands of HSV-negative women for the new trial will be a significant challenge, says Pamela McInnes, D.D.S, M.Sc.(Dent.), deputy director of NIAID's Division of Microbiology and Infectious Diseases. Between 50 and 80 percent of Americans are infected with HSV-1, typically during childhood, and about 1 in 5 people over age 12 is infected with HSV-2. The majority of those infected do not realize it, however, because symptoms of herpes disease can be mild or non-existent.

Symptoms following infection typically include blisters and then ulcers around the mouth or genitals. The virus may be transmitted through sexual or other skin-to-skin contact, and can even be spread when the infected person shows no symptoms. Once in the body, HSV migrates to nerve cells and remains there permanently. From time to time, an infected person may experience a herpes outbreak, but recurrences are typically less severe than the first occurrence. HSV can cause devastating illness in infants born to infected women, and the virus has been identified as a risk factor for the spread of HIV/AIDS in adults.

In the new trial, volunteers will be randomly assigned to receive either the candidate vaccine or a vaccine against hepatitis A. (This gives all participants a chance to be protected from a disease.) Neither the volunteers nor the researchers will know which vaccine a volunteer received until the close of the trial. Volunteers will be vaccinated at the start of the trial and at 1 and 6 months after the first injection. The women will be followed for 20 months after the initial vaccination to determine whether the candidate vaccine prevents HSV infection or disease.

Robert B. Belshe, M.D., of NIAID's Vaccine Evaluation and Treatment Unit at the Saint Louis University School of Medicine, will co-ordinate the clinical investigation.

The GSK vaccine is a subunit vaccine containing a piece of the HSV outer coat along with adjuvants, which help boost the immune system for a better response.

Women between the age of 18 and 30 who wish to be evaluated for possible inclusion in the trial should visit <http://www.niaid.nih.gov/dmid/stds/herpevac/>. Persons wishing to learn more about herpes can (view) the American Social Health Association. (Web site: <http://www.ashastd.org>)

NIAID is a component of the National Institutes of Health (NIH), which is an agency of the Department of Health and Human Services. NIAID supports basic and applied research to prevent, diagnose, and treat infectious and immune-mediated illnesses, including HIV/AIDS and other sexually transmitted diseases, illness from potential agents of bioterrorism, tuberculosis, malaria, autoimmune disorders, asthma and allergies.

Press releases, fact sheets and other NIAID-related materials are available on the NIAID Web site at <http://www.niaid.nih.gov>.

REFERENCE: LR Stanberry et al. Glycoprotein-D-adjuvant vaccine to prevent genital herpes. "The New England Journal of Medicine" 347:1652-61 (2002).

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