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NIAID Announces Contracts to Develop Vaccine Against H5N1 Avian Influenza

The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, has awarded two contracts to support the production and clinical testing of an investigational vaccine based on a strain of avian influenza, H5N1, which might have the potential to cause pandemic influenza. If a pandemic of H5N1 avian influenza were to occur in humans, production of such a vaccine on a commercial scale could be used to protect laboratory workers, public health personnel at risk and, if needed, the general public.

The new contracts were awarded to Aventis Pasteur Inc. of Swiftwater, PA, and to Chiron Corporation of Emeryville, CA. Both companies already manufacture inactivated influenza virus vaccines that are licensed for use during annual influenza seasons.

"The outbreak of H5N1 avian influenza again in Asia earlier this year, which resulted in 34 documented cases of human illness and 23 deaths, underscores the national and international imperative to develop new and improved medical tools to prepare for the threat of pandemic influenza," says Anthony S. Fauci, M.D., director of NIAID. "Vaccines are key to preparing for the public health emergency that pandemic influenza would entail."

Influenza is an important disease that causes significant death and disability in the United States every year. According to the U.S. Centers for Disease Control and Prevention, more than 100,000 cases of flu require hospitalization and as many as 36,000 people die from influenza or its complications annually. Pandemic influenza is much rarer, but much more deadly. Pandemics are global epidemics that emerge infrequently but unpredictably and involve strains of the flu virus to which humans have little or no immunity. The last pandemic swept the

globe in 1968; most public health experts believe the world is overdue for another one.

To develop their inactivated vaccines, the two companies will use a strain of H5N1 avian influenza taken from a Vietnamese patient in February 2004. With approval from the U.S. Food and Drug Administration, the investigational vaccines will then be tested for safety and immunogenicity in Phase I and Phase II clinical trials. These trials, to be conducted by NIAID's Vaccine and Treatment Evaluation Units (VTEUs), will study the vaccine in healthy adults first with subsequent studies planned in children and the elderly.

Until 1997, avian influenza had never been known to directly infect humans, but in that year an outbreak of avian influenza type H5N1 infected 18 people in Hong Kong, six of whom died. The virus did not spread easily between humans and did not result in a pandemic. Likewise, the outbreak of H5N1 avian influenza in humans in late 2003 and early 2004 did not result in a pandemic in part because it also did not spread easily from person to person.

Aventis Pasteur and Chiron will each produce between 8,000 and 10,000 doses of the investigational vaccine made through established techniques in which the virus is grown in eggs and then inactivated and further purified before being formulated into vaccines. The use of established techniques to develop the investigational vaccines will help to promote rapid licensing of commercial pandemic vaccines in the event of a pandemic outbreak.

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



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