U.S. Department of Health and Human Services
NIH News
National Institutes of Health

National Institute of Allergy and Infectious Diseases (NIAID)
http://www.niaid.nih.gov/

FOR IMMEDIATE RELEASE
Wednesday, July 22, 2009

Media Contact: Anne A. Oplinger
(301) 402-1663
niaidnews@niaid.nih.gov

NIAID Set to Launch Clinical Trials to Test 2009 H1N1 Influenza Vaccine Candidates

Scientists in a network of medical research institutions across the United States are set to begin a series of clinical trials to gather critical data about influenza vaccines, including two candidate H1N1 flu vaccines. The research will be under the direction of the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health.

"With the emergence of the 2009 H1N1 influenza virus, we have undertaken a collaborative and efficient process of vaccine development that is proceeding in stepwise fashion," says NIAID Director Anthony S. Fauci, M.D.

After the isolation and characterization of the virus, the U. S. Centers for Disease Control and Prevention generated and distributed a 2009 H1N1 seed virus to vaccine manufacturers for the development of vaccine pilot lots for testing in clinical trials.

"Now, NIAID will use our longstanding vaccine clinical trials infrastructure—the Vaccine and Treatment Evaluation Units—to help quickly evaluate these pilot lots to determine whether the vaccines are safe and to assess their ability to induce protective immune responses," says Dr. Fauci. "These data will be factored into the decision about how and if to implement a 2009 H1N1 flu immunization program this fall."

Initial studies will look at whether one or two 15 microgram doses of H1N1 vaccine are needed to induce a potentially protective immune response in healthy adult volunteers (aged 18 to 64 years old) and elderly people (aged 65 and older). Researchers also will assess whether one or two 30 microgram doses are needed. The doses will be given 21 days apart, testing two manufacturers' vaccines (Sanofi Pasteur and CSL Biotherapies). If early information from those trials indicates that these vaccines are safe, similar trials in healthy children (aged 6 months to 17 years old) will begin.

A concurrent set of trials will look at the safety and immune response in healthy adult and elderly volunteers who are given the seasonal flu vaccine along with a 15 microgram dose of 2009

(more)

H1N1 vaccine. The H1N1 vaccine would be given to different sets of volunteers either before, after, or at the same time as the seasonal flu vaccine. If early information from those studies indicates that these vaccines are safe, similar trials in healthy children (aged 6 months to 17 years old) will start.

A panel of outside experts will conduct a close review of the safety data from these trials to spot any safety concerns in real time. Information from these studies in healthy people will help public health officials develop recommendations for immunization schedules, including the optimal dosage and number of doses for multiple age and groups, including adults, the elderly, and children. Data may also be used to support decisions about the best recommendations for people in high risk groups, including pregnant women and people whose immune systems are weakened or otherwise compromised.

The trials are being conducted in a compressed timeframe in a race against the possible autumn resurgence of 2009 H1N1 flu infections that may occur at the same time as seasonal influenza virus strains begin to circulate widely in the Northern Hemisphere.

Close collaboration among NIAID, the U.S. Food and Drug Administration (FDA) and the Biomedical Advanced Research and Development Authority (a component of the Department of Health and Human Services) was key to launching the trials quickly while ensuring high standards. Following initial discussions between the agencies on trial design, NIAID prepared the protocols and submitted them to the FDA for review. FDA rapidly completed the necessary reviews and approved the trial protocols.

Since 1962, NIAID's Vaccine and Treatment Evaluation Units (VTEUs) have been intensively involved in the successful development and clinical testing of vaccines and treatments against many pathogens that threaten the health of people in the United States and around the world. Among the vaccines tested have been those that prevent seasonal influenza, H5N1 avian influenza and pneumococcal pneumonia.

The VTEU network consists of eight university research hospitals and medical organizations across the United States that provide a ready resource for conducting clinical trials that evaluate vaccines and treatments for a wide array of infectious diseases.

An important strength of the VTEUs is their ability to rapidly enroll large numbers of volunteers into trials and to immunize the volunteers in a safe, effective and efficient manner. This rapid-response capability is especially important for testing vaccines designed to counteract emerging public health concerns. Results are expected to be available weeks after the trials begin.

NIAID's Vaccine and Treatment Evaluation Units include the following:

- Baylor College of Medicine, Houston
- Children's Hospital Medical Center, Cincinnati

- Emory University, Atlanta
- Group Health Cooperative, Seattle
- Saint Louis University, St. Louis
- University of Iowa, Iowa City
- University of Maryland School of Medicine, Baltimore
- Vanderbilt University, Nashville, Tenn.

Further information about the five trials can be found at ClinicalTrials.gov at the following links:

- 09-0053 Unadjuvanted Sanofi Pasteur H1N1 Influenza Vaccine Given at Two Dose Levels to Healthy Adult and Elderly Populations
  - NCT00943631 (http://clinicaltrials.gov/show/NCT00943631)
- 09-0043 Unadjuvanted CSL H1N1 Influenza Vaccine Given at Two Dose Levels to Healthy Adult and Elderly Populations
  - NCT00943488 (http://clinicaltrials.gov/show/NCT00943488)
- 09-0039 Licensed Seasonal Flu Vaccine Given Together or Sequentially with Unadjuvanted Sanofi Pasteur H1N1 Influenza Vaccine in Healthy Adult and Elderly Populations
  - NCT00943878 (http://clinicaltrials.gov/show/NCT00943878)
- 09-0054 Unadjuvanted Sanofi Pasteur H1N1 Influenza Vaccine Administered at Two Dose Levels to Children
  - NCT00944073 (http://clinicaltrials.gov/show/NCT00944073)
- 09-0047 Licensed Seasonal Flu Vaccine Given Together or Sequentially with Unadjuvanted Sanofi Pasteur H1N1 Influenza Vaccine in Previously Primed Children
  - NCT00943202 (http://clinicaltrials.gov/show/NCT00943202)

For more information on influenza, visit www.flu.gov for one-stop access to U.S. government information on avian and pandemic influenza. Also, see http://www3.niaid.nih.gov/topics/Flu/.

NIAID conducts and supports research—at NIH, throughout the United States, and worldwide—to study the causes of infectious and immune-mediated diseases, and to develop better means of preventing, diagnosing and treating these illnesses. News releases, fact sheets and other NIAID-related materials are available on the NIAID Web site at http://www.niaid.nih.gov.

The National Institutes of Health (NIH)—*The Nation's Medical Research Agency*—includes 27 Institutes and Centers and is a component of the U. S. Department of Health and Human Services. It is

the primary federal agency for conducting and supporting basic, clinical and translational medical research, and it investigates the causes, treatments and cures for both common and rare diseases. For more information about NIH and its programs, visit *http://www.nih.gov*.