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FDA Approves First U.S. Vaccine for Humans Against the Avian Influenza Virus H5N1

The U.S. Food and Drug Administration (FDA) today announced the first approval in the United States of a vaccine for humans against the H5N1 influenza virus, commonly known as avian or bird flu.

The vaccine could be used in the event the current H5N1 avian virus were to develop the capability to efficiently spread from human to human, resulting in the rapid spread of the disease across the globe. Should such an influenza pandemic emerge, the vaccine may provide early limited protection in the months before a vaccine tailored to the pandemic strain of the virus could be developed and produced.

"The threat of an influenza pandemic is, at present, one of the most significant public health issues our nation and world faces," said Andrew C. von Eschenbach, M.D., Commissioner of Food and Drugs. "The approval of this vaccine is an important step forward in our protection against a pandemic."

The H5N1 virus is one version of the influenza A virus commonly found in birds. Unlike seasonal influenza, where infection ranges from mild to serious symptoms in most people, the disease caused by H5N1 is far more severe and happens quickly, with pneumonia and multi-organ failure commonly seen.

While there have been no reported human cases of H5N1 infection in the United States, almost 300 people worldwide have been infected with this virus since 2003 and more than half of them have died. To date, H5N1 influenza has remained primarily an animal disease but should the virus acquire the ability for sustained transmission among humans, people will have little immunity to this virus and the potential for an influenza pandemic would have grave consequences for global public health.

"The timing and severity of an influenza pandemic is uncertain, but the danger remains very real," said Jesse L. Goodman, M.D., M.P.H., Director of FDA's Center for Biologics Evaluation and Research. "We are working closely with other government agencies, global partners and the vaccine industry to facilitate the development, licensure and availability of needed supplies of safe and effective vaccines to protect against the pandemic threat."

The vaccine was obtained from a human strain and is intended for immunizing people 18 through 64 years of age who could be at increased risk of exposure to the H5N1 influenza virus contained in the vaccine. H5N1 influenza vaccine immunization consists of two intramuscular injections, given approximately one month apart. The manufacturer, sanofi pasteur Inc., will not sell the vaccine commercially. Instead, the vaccine has been purchased by the federal government for inclusion within the U.S. Strategic National Stockpile for distribution by public health officials if needed. The vaccine will be manufactured at sanofi pasteur's Swiftwater, Pa., facility.

A clinical study was conducted to collect safety information and information on recipient's immune responses and to determine the appropriate vaccine dose. A total of 103 healthy adults received a 90 microgram dose of the vaccine by injection followed by another 90 microgram dose 28 days later. In addition, there were approximately 300 healthy adults who received the vaccine at doses lower than 90 micrograms and a total of 48 who received a placebo injection.

The vaccine was generally well tolerated, with the most common side effects reported as pain at the injection site, headache, general ill feeling and muscle pain. The study showed that 45 percent of individuals who received the 90 microgram, two-dose regimen developed antibodies at a level that is expected to reduce the risk of getting influenza. Although the level of antibodies seen in the remaining individuals did not reach that level, current scientific information on other influenza vaccines suggests that less than optimal antibody levels may still have the potential to help reduce disease severity and influenza-related hospitalizations and deaths. Additional information on this H5N1 influenza vaccine is being collected on safety and effectiveness in other age groups and will be available to FDA in the near future.

With the support of FDA, the U.S. National Institutes of Health and other government agencies, sanofi pasteur and other manufacturers are working to develop a next generation of influenza vaccines for enhanced immune responses at lower doses, using technologies intended to boost the immune response. Meanwhile, the approval and availability of this vaccine will enhance national readiness and the nation's ability to protect those at increased risk of exposure.

The U.S. Strategic National Stockpile is maintained by the U.S. Centers for Disease Control and Prevention. It contains large quantities of medicine and medical supplies to protect the American public if there is a public health emergency, which can be delivered to any state in the United States within 12 hours. For more information on the government's preparedness efforts, visit: www.pandemicflu.gov.

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Product Approval Information - Licensing Action

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