Pandemic Flu Vaccine Under Study for Asthmatics

BY MICHELE G. SULLIVAN

A new phase II trial will test the safety and efficacy of the pandemic influenza A(H1N1) vaccine on patients with mild to severe asthma.

Although the vaccine has already been approved as safe and effective in the general population, additional studies are necessary to confirm its effect on those with asthma—especially those who take glucocorticoid medications, Dr. Anthony Fauci said in a statement.

"People with severe asthma often take high doses of glucocorticoids that can suppress their immune system, placing them at greater risk for infection and possibly serious disease caused by 2009 H1N1 influenza virus," said Dr. Fauci, director of the National Institute of Allergy and Infectious Disease (NIAID). "We need to determine the optimal dose of 2009 H1N1 influenza vaccine that can be safely administered to this at-risk population and whether one or two doses are needed to provide an immune response that is predictive of protection."

The study, sponsored by NIAID and the National Heart, Lung, and Blood Institute, plans to enroll 350-400 healthy subjects aged 12 years and older with mild, moderate, or severe asthma. Participants will be stratified into two groups: those with mild to moderate versus those with severe asthma. All participants will be randomly assigned to receive either a high-dose (30 mcg) or low-dose (15 mcg) H1N1 vaccine. Both vaccine dosages will be administered in two intramuscular injections 21 days apart. Participants assigned to the higher dose (30 mcg) will receive two injections of the 15-mcg vaccine at each administration. ■