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Emory to Participate in NIH Clinical Trials Testing 2009 H1N1 Influenza Vaccines

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ATLANTA—As part of a nationwide clinical trials network, Emory University will participate in several clinical studies gathering data about 2009 influenza vaccines, including two new H1N1 flu vaccines. The clinical trials will be conducted through the Vaccine and Treatment Evaluation Units (VTEUs) of the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH).

NIAID Director Anthony S. Fauci, MD, today announced the launch of the new series of clinical trials.

Emory will begin recruiting healthy adults, seniors and children into these clinical trials, beginning in early August. The trials are being conducted in a compressed timeframe because of the possible fall resurgence of H1N1 flu infections that may coincide with the circulation of new seasonal flu strains in the Northern Hemisphere.

The trials are expected to gather critical information that will allow the NIH to quickly evaluate the new vaccines to determine whether they are safe and effective in inducing protective immune responses. The results will help determine if and how to begin a fall 2009 H1N1 flu vaccination program.

The United States government declared the H1N1 outbreak a public health emergency in April and two months later, the World Health Organization classified the outbreak a pandemic, reflecting its widespread nature.

“These clinical trials are critical in preparing for this fall’s vaccination program and in possibly preventing a widespread H1N1 pandemic when the flu season begins. We are pleased through our participation to include Emory and the city of Atlanta in this important national public health effort,” says Mark Mulligan, MD, principal investigator of the Emory VTEU, professor of medicine in Emory University School of Medicine and executive director of the Hope Clinic of the Emory Vaccine Center. “Time is critical. We are in a race against the return of the flu season this fall.”

Two adult clinical trials at Emory will enroll healthy adults and seniors and will be conducted at the Emory Vaccine Center’s Hope Clinic in downtown Decatur.

Two pediatric clinical trials will be conducted at the Emory-Children's Center and will evaluate vaccine safety, tolerability and immune responses in infants older than 6 months, toddlers, children and adolescents up to 18 years.

"Children and young adults are considered among the most vulnerable populations for new and emerging strains of influenza, such as the current H1N1 pandemic," says Harry Keyserling, MD, Emory professor of pediatric infectious diseases and co-director of the Emory VTEU. "Vaccines are our most effective public health weapon against influenza. We are pleased that Emory will participate in these essential studies."

In addition to Mulligan and Keyserling, additional investigators in the flu clinical trials at Emory will include Srilatha Edupuganti, MD, Nadine Rouphael, MD, Paul Spearman, MD and Allison Ross, MD.

The two new H1N1 vaccines were manufactured by Sanofi Pasteur and CSL Biotherapies. Researchers also hope to determine whether 2009 H1N1 flu vaccine can be given at the same time as or shortly before or after the seasonal flu vaccine.

"We will also be evaluating the dosage required, and whether one dose versus two is needed," says Mulligan. "With pandemic influenza, the population lacks prior immunity to the flu virus, so vaccination may require higher or more doses than for seasonal flu. Older persons may respond better to the novel H1N1 vaccine if they have been exposed to a similar H1N1 virus years earlier. This could also explain why most of the current pandemic cases are occurring in younger persons."

The VTEUs were established in 1962 as a vital research component of the NIAID. The units conduct clinical trials for all infectious diseases other than HIV/AIDS. They have conducted hundreds of clinical studies over the past four decades. Emory was designated a VTEU site in 2007 and received a seven-year contract of approximately \$23.7 million.

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 vaccine designed to counteract emerging public health concerns. Results are expected to be available weeks after the trials begin.

In addition to Emory, VTEU sites are Baylor College of Medicine, Houston; Children's Hospital Medical Center, Cincinnati; Group Health Cooperative, Seattle; Saint Louis University, St. Louis; University of Iowa, Iowa City; University of Maryland School of Medicine, Baltimore; and Vanderbilt University, Nashville.

They will be joined for these studies by Children's Mercy Hospital in Kansas City and Duke University Medical Center.

For more information about the Emory flu clinical trials, call 877-424-HOPE (4673) for the adult and senior studies, or 404-727-4044 for the pediatric studies, or vaccine@emory.edu for further information about the upcoming trials.

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