Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

Title of Trial: Phase 1 Evaluation of the Safety and Immunogenicity of Live Influenza A Vaccine H7N9 (6-2) AA ca Recombinant (A/Anhui/1/2013 (H7N9) x A/Ann Arbor/6/60 ca), a Live Attenuated Virus Vaccine Candidate for Prevention of Influenza H7N9 Disease in the Event of a Pandemic

Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov): NCT1995695

Authors/sponsors: Dr John Treanor, University of Rochester/National Institute of Allergy and Infectious Diseases (NIAID)

Study Design: Randomized, open label

Vaccine: H7N9

Manufacturer: MedImmune

Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector): Live attenuated

Adjuvant: None

Delivery system/site: IM

Doses (antigen and adjuvant): $10^7$ FFU/dose

- Experimental: Group 1: One Vaccine Dose and One Booster Vaccine Dose
  Participants will receive one dose of live attenuated H7N9 A/Anhui/13 ca influenza virus vaccine at study entry. They will then receive one dose of inactivated subvirion H7N9 influenza vaccine on Day 98.

- Experimental: Group 2: Two Vaccine Doses and One Booster Vaccine Dose
  Participants will receive two doses of live attenuated H7N9 A/Anhui/13 ca influenza virus vaccine: one dose at study entry and one dose on Day 28. They will then receive one dose of inactivated subvirion H7N9 influenza vaccine on Day 98.

Study population: 48 volunteers of 18-49 years

Age range: Health status: Healthy

Specific inclusion criteria:

- Adult males and non-pregnant females between 18 years and 49 years of age, inclusive.
- Children will not be recruited or enrolled in this study because they are not in the apparent risk group, and for safety considerations and because of the need for isolation.
- General good health, without significant medical illness, physical examination findings, or significant laboratory abnormalities as determined by the investigator
- Agree to storage of blood specimens for future research
- Available for the duration of the trial
- Willingness to participate in the study as evidenced by signing the informed consent document
- Female participants of child-bearing potential must agree to use effective birth control methods for the duration of the study (for example, pharmacologic contraceptives including oral, parenteral, and transcutaneous delivery; condoms with spermicide; diaphragm with spermicide; intrauterine device; abstinence from heterosexual intercourse; surgical sterilization). All female participants will be considered being of child-bearing potential except those who have undergone hysterectomy and those in whom menopause occurred at least 1 year prior to the study.
Clinical Endpoints Assessed:

Safety assessments:
• Frequency of vaccine-related reactogenicity events that occur during the acute monitoring (inpatient) phase of the study
• Area under the curve (AUC) of nasal virus shedding after each dose of vaccine, as assessed by liquid titration of nasal secretions on Madin Darby canine kidney (MDCK) cells at 33°C
• Vaccine virus shedding on one or more days on Days 2 through 9 as assessed by culture or real-time reverse transcriptase polymerase chain reaction (rRT-PCR)

Immunogenicity assessments:
• Evidence of a 4-fold or greater increase in either hemagglutination inhibition (HAI) or microneutralization (MN) antibody comparing pre-vaccination to either Day 29 or Day 56 post-dose two samples
• Development of serum antibody assessed by either HAI or MN assays

Results: Not yet available

Safety:
Immunogenicity

GMTs:

GMT Ratios (post:pre):

Per cent responding (4 fold or greater rise and definition for reporting):

Per cent responders at specified tite:

Others assays:

Status of trial (ongoing/completed): 2013-2014 (ongoing)