Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

Title of Trial: An Open-Label Phase I Study of the Safety and Immunogenicity of an Investigational H1 DNA Influenza Vaccine, VRC-FLUDNA057-00-VP, in Healthy Adults 18-70 Years Old.

Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov): NCT00973895

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Study Design (including the phase of clinical trial): VRC 308 is an open-label Phase I study to evaluate the safety, tolerability, and immunogenicity of 3-injection vaccination regimen with an investigational plasmid DNA vaccine that encodes for H1 hemagglutinin (HA) of an H1N1 influenza virus. All study participants will be offered to receive an additional optional booster immunization with licensed inactivated monovalent H1N1 influenza vaccine. The hypothesis is that the DNA vaccine will be safe for human administration and will elicit an antibody response.

Vaccine subtype: Prime/boost DNA vaccine and inactivated virus vaccine

Virus: DNA plasmid and inactivated vaccine encoding H1N1 swine flu 2009 strain

Manufacturer: DNA vaccine - NIH, USA; inactivated vaccine - Novartis

Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector): DNA vaccine and inactivated virus

Adjuvant: None

Delivery system/site: IM by Biojector for DNA vaccine and IM by needle/syringe for inactivated vaccine

Doses (antigen and adjuvant, number of doses, intervals between administrations): DNA vaccine – 4000 µg, inactivated vaccine - 15µg

Study population: Adults

Number of subjects involved: 20

Age range: 18-70 years old

Health status: Healthy volunteers

Special inclusion/exclusion criteria: None

Clinical Endpoints Assessed:
The primary objectives are to evaluate the safety and tolerability of the vaccine regimens. Secondary and exploratory objectives are related to the immunogenicity of the vaccine regimens.

Safety assessments:
• Local reactogenicity signs and symptoms
• Systemic reactogenicity signs and symptoms
• Laboratory measures of safety
• Adverse and serious adverse experiences

Immunogenicity assessments (immunoassay type):
HI (type of RBC used): HAI assay using horse erythrocytes
NT (type of neutralization assay): Pseudotyped lentivirus reporter assay
SRH: Not done

ELISpot: to determine frequency of T cells producing IFN-γ in response to pools of overlapping peptides representing influenza antigens
ICS: to determine frequency of CD4+ and CD8+ cells that produce IL-2 or IFN-γ in response to pools of overlapping peptides representing influenza antigens

Results:
Safety: The vaccine was safe and well tolerated
Reactogenicity: There was one report of moderate headache and two reports of moderate malaise. Otherwise all local and systemic reactogenicity was reported as none or mild.
SAEs: There were no SAEs.
Immunogenicity: Analysis is ongoing.


Date envisaged for availability of results, if not yet available: Manuscript is in preparation.