Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

Title of Trial: Clinical evaluation of a plant-derived H1N1 recombinant hemagglutinin influenza vaccine
Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov): 
Authors/sponsors: Vidadi Yusibov
Study Design: Phase 1 single blind placebo- controlled single center trial
Vaccine Strain: H1N1
Manufacturer: Center for Molecular Biotechnology, Fraunhofer, USA
Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector): Plant-derived hemagglutinin
Adjuvant: Alhydrogel (0.3%)
Delivery system/site: intramuscular injection
Doses (antigen and adjuvant): 15µg, 45 µg, 90 µg of antigen. Two doses at days 0 and 21

Study population: 80
Age range 18-50 Health status: Healthy volunteers
Specific inclusion criteria: Healthy male or female subjects
Specific exclusion criteria: Received any vaccine including seasonal 'flu vaccine within 30 days of first dose of study vaccine or have pre-study HI titer of >1:40
Presently receiving medication affecting immune system (corticosteroids, etc)
Presence of medical condition associated with impaired immune response
Received any investigational product within 30 days prior to receiving study vaccine

Clinical Endpoints Assessed:
Safety assessments: To date, at 3 months follow-up, no serious adverse events were reported. No subject discontinued due to adverse event. Local reactions (pain, tenderness, erythema, induration) were mild.
Immunogenicity assessments:
- Immunoassay type:
  - HI
Neutralization (type of neutralization assay):
Others:
Results:
Safety:

Immunogenicity: No results publically available
  GMTs
  GMT Ratios (post:pre)
Per cent responding (4 fold or greater rise and definition for reporting):
Per cent responders at specified titer:
Others:

Status of trial (ongoing/completed): ongoing