Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

Title of Trial: Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov):
Authors/sponsors: Manon Cox/
Study Design (including the phase of clinical trial): Phase 1-II.

Vaccine subtype: H1N1 Virus: A/California/7/2009
Manufacturer: Protein Sciences Corporation
Type (whole virus/subviorin/subunit/live/recombinant/DNA/vector): recombinant HA incorporated into Baculovirus as a vector, SF+
insect cells used as substrate
Adjuvant: Inulin as adjuvant
Delivery system/site: Intramuscular injection
Doses (antigen and adjuvant, number of doses, intervals between administrations): 3, 11 and 45 µg of viral protein per dose; two
doses at day 0 and 21

Study population
Number of subjects involved: 275 Age range: 18-49
Health status: Health volunteers
Special inclusion/exclusion criteria:

Clinical Endpoints Assessed
Safety assessments:
Immunogenicity assessments:
immunoassay type
HI (type of RBC used): Horse RBC, 4 HA units of antigen
NT (type of neutralization assay):
SRH

Results
Safety:
Reactogenicity:
AEs:
SAEs:

Immunogenicity

HI or NT:
GMTs:
GMT Ratios (post:pre):
HI≥40 after one dose)

8.4 (45g+Inulin)
2.4 (11µg+Inulin)
2.1 (3µg+Inulin)
3.1 (45µg no Inulin)
2.4 (11µg no Inulin)
2.0 (3µg no Inulin)
Per cent responding (4 fold increase):
HI≥4 fold increase after one dose
80%  45µg+Inulin
33%  (11µg+Inulin)
23%  (3µg+Inulin)
42%  (45µg no Inulin)
26%  (11µg no Inulin)
27%  (3µg no Inulin)

Per cent responders at specified titer:
HI≥40 after one dose
80%  (45µg+Inulin)
76%  (11µg+Inulin)
50%  (3µg+Inulin)
58%  (45µg no Inulin)
74%  (11µg no Inulin)
41%  (3µg no Inulin)

SRH:
Per cent with titre (in mm²)

Current status of the clinical trial (completed, ongoing, in preparation): Completed

Date envisaged for availability of results, if not yet available:

Planned time schedule for next phase of development: