Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

Title of Trial: Immunogenicity and safety after one dose of adjuvanted and non-adjuvanted split-virion H1N1 vaccine.
Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov): NCT00956111
Authors/sponsors:
Study Design (including the phase of clinical trial): Randomized, double – blind and control trial

Vaccine subtype: H1N1   Virus: A/California/07/2009
Manufacturer: Sinovac Biotech, China
Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector): split – virion vaccine
Adjuvant: AL(OH)3
Delivery system/site: Intramuscular injection
Doses (antigen and adjuvant, number of doses, intervals between administrations): 7.5 µg, 15 µg and 30 µg per dose. Two doses at days 0 and 21

Study population/Number of subjects involved: 1300      Age range: Three age groups: 3-11 years, 12-17 years and 18-60 years
Health status: Health volunteers
Special inclusion/exclusion criteria:

Clinical Endpoints Assessed
Safety assessments:
Immunogenicity assessments:
   immunoassay type
   HI (type of RBC used):
   NT (type of neutralization assay):
   SRH

Results
Safety:
Reactogenicity:
AEs: All formulations were well tolerated with no serious adverse events. Most local and systemic reactions were mild or moderate.
SAEs:

Immunogenicity

HI :
GMTs :
GMT Ratios (post:pre):
   Fold increase in HI after one dose in age groups:
   3-60y
   15.1 - 53.1     (15µg no Alum)

Per cent responding (4 fold increase):
HI≥40 after one dose in age groups:
   3-60y
   81-98%     (15µg no Alum)
Per cent responders at specified titer:
HI ≥40 after one dose in age groups:
3-60y 81-98% (15µg no Alum)

One dose of the all formulations induced satisfactory HI response complying
with the onternationalle accepted licensure criteria. The dose –depended
relashionship was generally found. The highest immune reaponse was observed
in adults, adolescents and children after one dose of 30 µg non-adjuvanted split-
virion vaccine. An unexpected finding was that aluminium adjuvant did not boost
the immune response.

SRH:
Per cent with titre (in mm²) None

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: