Pandemic Influenza Vaccine Clinical Trial Abstract

Minimum information:

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

Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector):
Inactivated whole virion vaccine
Adjuvant: AL(OH)3
Delivery system/site: Intramuscularly
Doses (antigen and adjuvant, number of doses, intervals between administrations): Two doses at days 0 and 28, 5µg of viral protein per dose

Study population
Number of subjects involved: 70 children  Age range: 12-17 years
Health status: Healthy
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:
SAEs: Two and one participants respectively reported severe reactions after the first dose of 10- and 15µg vaccine. It seems that the incidence and severity of adverse reactions were not accepted in adolescents.

Immunogenicity

HI

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<tr>
<th>HI ≥40</th>
<th>HI ≥4 fold increase</th>
<th>GMT ratio (post:pre)</th>
</tr>
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<tbody>
<tr>
<td>45%</td>
<td>45%</td>
<td>6.0</td>
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NT: No data

SRH: No data
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: