Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

Title of Trial:
Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov):
Authors/sponsors:  Sinovac Biothec
Study Design (including the phase of clinical trial):  Phase Ib 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, 10µg of viral protein per dose

Study population  Number of subjects involved:  70 elderly  Age range: 60-71 years
Health status:  Healthy 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:  The two doses were well tolerated in older adults, only one participant reported moderate fever in the 10µg group
SAEs:

Immunogenicity

<table>
<thead>
<tr>
<th>HI</th>
<th>HI≥40</th>
<th>HI≥4 fold increase</th>
<th>GMT ratio (post:pre)</th>
</tr>
</thead>
<tbody>
<tr>
<td>49%</td>
<td>48%</td>
<td></td>
<td>5.5</td>
</tr>
</tbody>
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SRH:  No data
Per cent with titre (in mm²)

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

Date envisaged for availability of results, if not yet available:
Planned time schedule for next phase of development: