Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

Title of Trial: Development of human influenza H5N1 vaccine in Japan
Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov): 1 site
Authors: Osamu Kogawara MS, The Kitasato Institute, Research center for biologicals
Sponsors: The Kitasato Institute, Japan
Study Design: 20 healthy adults per group, total 120 adults; 3 doses on days 0 and 21 with subcutaneous or intramuscular. Phase I.
Vaccine: Egg grown, formalin inactivated H5N1, Manufacturer: Kitasato Institute, Japan

Study population:
Age range: Adults 20-40 years old
Health status: health

Clinical Endpoints Assessed:
Safety assessments: clinical laboratory tests (blood, urine), clinical signs and symptoms, physical checkup (body temperature, blood pressure, pulse rate, ECG)
Immunogenicity assessments: antibody responses were measured at days 21 and 42
Imunoassay type: hemagglutination and neutralization
HI (type of RBC used): Horse RBCs
Neutralization (type of neutralization assay): microneutralization

Results
Safety: Vaccines are safe and well tolerated.
Reactogenicity: Not only the frequency of the local reaction but also the systemic reactive frequency was dose-dependent.

Adverse reactions:

<table>
<thead>
<tr>
<th></th>
<th>Admin.Route: SC</th>
<th></th>
<th>Admin.Route: IM</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1.7µg</td>
<td>5µg</td>
<td>15µg</td>
<td>1.7µg</td>
</tr>
<tr>
<td>Local reactions (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Redness</td>
<td>65.0</td>
<td>70.0</td>
<td>95.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Swelling</td>
<td>20.0</td>
<td>25.0</td>
<td>80.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Itches</td>
<td>25.0</td>
<td>15.0</td>
<td>25.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Induration</td>
<td>35.0</td>
<td>30.0</td>
<td>55.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Injection site warmth</td>
<td>15.0</td>
<td>15.0</td>
<td>55.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Systemic reactions(%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>15.0</td>
<td>35.0</td>
<td>30.0</td>
<td>5.0</td>
</tr>
<tr>
<td>Weariness</td>
<td>15.0</td>
<td>15.0</td>
<td>20.0</td>
<td>15.0</td>
</tr>
</tbody>
</table>

SAEs: No SAEs were found

Immunogenicity: Results of Neutralization are presented after 2 doses
GMTs
SC: 12.7 (1.7µg), 29.9(5µg), 41.5(15µg)
IM: 23.0 (1.7µg), 47.6(5µg), 58.8(15µg)

Per cent responding (4 fold or greater rise and definition for reporting):
SC: 25.0% (1.7µg), 57.9%(5µg), 73.7%(15µg)
IM: 50.0% (1.7µg), 75.0%(5µg), 100.0%(15µg)
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