Title of Trial: Safety and reactogenicity profile of an adjuvanted H5N1 whole virus vaccine in adults within safety trial

Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov):

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Study Design (including the phase of clinical trial): Phase IV of clinical trial

Vaccine subtype: 

Type: whole virus (Indonesia strain manufactured by Biken, Anhui strain manufactured by Kitazato) 

Adjuvant: Al(OH)3 

Delivery system/site: intramuscularly 

Doses (antigen and adjuvant, number of doses, intervals between administrations): 15 μg of viral HA protein 0.15mg of Al(OH)3

H5N1 vaccine were administered 21 days apart from 1st vaccination. Local reactions and general conditions were recorded by themselves between the day of 1st vaccination and 30 days after 2nd vaccination.

Study population

Number of subjects involved: 2726 vaccinated with Indonesia strain, 2835 vaccinated with Anhui strain. 

Age range: 20-60 years old 

Health status: healthy adults 

Special inclusion/exclusion criteria: prior infection with H5N1 Anaphylaxic episode to vaccine contents Chronic cardiac diseases and pulmonary diseases

Clinical Endpoints Assessed

Safety assessments: clinical reactogenicity

Immunogenicity assessments: no assessment

immunoassay type 
HI (type of RBC used): 
NT (type of neutralization assay): 
SRH

Results

Safety: Reactogenicity:

<table>
<thead>
<tr>
<th></th>
<th>Indonesia</th>
<th></th>
<th>Anhui</th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1st</td>
<td>2nd</td>
<td>1st</td>
<td>2nd</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Local reactions overall</td>
<td>64.2%</td>
<td>46.8%</td>
<td>67.9%</td>
<td>49.6%</td>
<td></td>
<td></td>
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<tr>
<td>Redness</td>
<td>19.3</td>
<td>10.6</td>
<td>22.8</td>
<td>14.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>45.2</td>
<td>42.7</td>
<td>46.1</td>
<td>45.7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Itching</td>
<td>11.3</td>
<td>6.5</td>
<td>15.9</td>
<td>15.9</td>
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<td></td>
</tr>
<tr>
<td>Thermity</td>
<td>12.0</td>
<td>5.4</td>
<td>14.5</td>
<td>7.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Swelling</td>
<td>10.5</td>
<td>6.5</td>
<td>14.6</td>
<td>9.1</td>
<td></td>
<td></td>
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<tr>
<td>general reactions</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>headache</td>
<td>14.2</td>
<td>8.0</td>
<td>14.2</td>
<td>8.2</td>
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<td></td>
</tr>
<tr>
<td>fatigue</td>
<td>23.4</td>
<td>13.1</td>
<td>21.4</td>
<td>11.5</td>
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<td></td>
</tr>
<tr>
<td>fever(&gt;37.5°C)</td>
<td>2.1</td>
<td>0.5</td>
<td>2.3</td>
<td>0.9</td>
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<tr>
<td>SAE</td>
<td>0.11</td>
<td>0.07</td>
<td>0.04</td>
<td>0.07</td>
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</tbody>
</table>

AEs:
SAEs: 3 cases at the 1st vaccination with Indonesia strain, 2 cases at the 2nd vaccination with Indonesia strain, 1 case at the 1st vaccination with Anhui strain, and 2 cases at 2nd vaccination with Anhui strain. Two cases might be related to vaccination. The first case had fever within 24 hours after vaccination. He was administered with NSAID to suside the fever, which induced asthma attack, since he had had episode of aspyrin-induced asthma. The second case also had fever within 24 hours after vaccination. Since he was nervous, he had hyperventilation probable due to fear for fever. The other 6 cases were not related to vaccine.

Immunogenicity: not assessed

**HI or NT:**
GM Ts:
GMT Ratios (post:pre):
Per cent responding (4 fold increase):
Per cent responders at specified titer:

**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: