Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

Title of Trial: Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov):
Authors/sponsors: Larise Roudenko/Microgen
Study Design (including the phase of clinical trial):

Vaccine subtype: H1N1 pandemic  Virus: A/17/California/2009/38
Manufacturer: Microgen/ Institute of Experimental Medicine, Russia

Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector):
Live attenuated vaccine

Adjuvant: None

Delivery system/site: Intranasal administration

Doses (antigen and adjuvant, number of doses, intervals between administrations):
Two doses at days 0, 10 or 0, 21

10^6.5 EID/50 - for adults and 10^7.0 EID/50 - for children and elderly

Study population Number of subjects involved: 180
Age range: Three age groups:
12 - 18, 18 – 50 and 60

Health status: Healthy

Clinical Endpoints Assessed
Safety assessments:
Immunogenicity assessments:

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

Results
Safety:
Reactogenicity:

<table>
<thead>
<tr>
<th></th>
<th>Temperature</th>
<th>Systemic reactions</th>
<th>Local reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>37.1-37.5</td>
<td>&gt;38.538.5</td>
<td></td>
</tr>
<tr>
<td>First vaccination</td>
<td>37.6-38.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaccine</td>
<td>11%</td>
<td>0%</td>
<td>2%</td>
</tr>
<tr>
<td>Placebo</td>
<td>1%</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

Revaccination

<table>
<thead>
<tr>
<th></th>
<th>Temperature</th>
<th>Systemic reactions</th>
<th>Local reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>37.1-37.5</td>
<td>&gt;38.538.5</td>
<td></td>
</tr>
<tr>
<td>Vaccine</td>
<td>1%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Placebo</td>
<td>1%</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

SAEs: None

Immunogenicity
HI or NT:

GMT Ratios (post:pre):
Fold increase in HI (after 1 or 2 doses):

<table>
<thead>
<tr>
<th>Age Group</th>
<th>1 dose</th>
<th>2 doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>12-18y</td>
<td>12-&lt;18y</td>
<td>18-50y</td>
</tr>
<tr>
<td>3.1</td>
<td>6.7</td>
<td>-</td>
</tr>
</tbody>
</table>

Per cent responding (4 fold increase):

<table>
<thead>
<tr>
<th>Age Group</th>
<th>1 dose</th>
<th>2 doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>12-18y</td>
<td>41%</td>
<td>4%</td>
</tr>
<tr>
<td>18-50y</td>
<td>4%</td>
<td>7%</td>
</tr>
<tr>
<td>60y</td>
<td>83%</td>
<td>40%</td>
</tr>
</tbody>
</table>

Per cent responders at specified titer:

<table>
<thead>
<tr>
<th>Age Group</th>
<th>1 dose</th>
<th>2 doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>12-18y</td>
<td>45%</td>
<td>2%</td>
</tr>
<tr>
<td>18-50y</td>
<td>2%</td>
<td>0%</td>
</tr>
<tr>
<td>60y</td>
<td>83%</td>
<td>32%</td>
</tr>
</tbody>
</table>

Studies of 10 and 21 days regimen between two doses have shown that 21 day interval was optimal for immunogenicity.

Immunogenicity results based on cumulative data of different assays such as HAI, ELISA IgG, ELISA IgA and cytokine test have shown the possibility to recommend single dose vaccination for different age groups.

**SRH:**

<table>
<thead>
<tr>
<th>Per cent with titre (in mm²)</th>
<th>Completed</th>
</tr>
</thead>
</table>

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

Date envisaged for availability of results, if not yet available:

Planned time schedule for next phase of development: