Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

**Title of Trial:** Phase I and II clinical studies in adults to assess safety, reactogenicity and immunogenicity of inactivated subunit influenza vaccine against H1N1v (A/California/07/2009)

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

**Authors/sponsors:** Dr I. Krasilnikov, Dr A. Mironov/Microgen, Russia

**Study Design (including the phase of clinical trial):**

Phase I: to evaluate tolerability and reactogenicity of the experimental vaccine.
Phase II: to evaluate safety, reactogenicity and immunogenicity of the experimental vaccine.

**Vaccine subtype:** H1N1 Virus: Microgen State Scientific Industrial Company, Russia

**Manufacturer:** Microgen State Scientific Industrial Company, Russia

**Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector):**
Inactivated subunit

**Adjuvant:** AL(OH)3

**Delivery system/site:** IM

**Doses (antigen and adjuvant, number of doses, intervals between administrations):** 15 µg per dose, two dosed on days 0 and 28

**Study population**

- **Number of subjects involved:** 140
- **Age range:** 18-60
- **Health status:** Healthy volunteers

**Special inclusion/exclusion criteria:**

**Clinical Endpoints Assessed**

Safety assessments:

Immunogenicity assessments:

- **immunoassay type**
  - HI (type of RBC used): HI with horse erytrocites
  - NT (type of neutralization assay): Microneutralization

- **SRH:** No

**Results**

**Safety:**

Reactogenicity:

- **AEs:**

  % of reactogenicity events during 1-7 days after vaccination (phase I-II):

<table>
<thead>
<tr>
<th>Local reactions</th>
<th>Systemic reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>79%</td>
<td>87%</td>
</tr>
<tr>
<td>21%</td>
<td>21%</td>
</tr>
<tr>
<td>0%</td>
<td>1%</td>
</tr>
</tbody>
</table>

  **Mid**

**SAEs:** No

After vaccination with Pandeflu vaccine candidate there were no detections of abnormal reactions in post-vaccination period. Slightly shaped local and mild systemic reactions were a short period (1-3 days) and did not much influence a good state of health of recipients.
Immunogenicity

**HI or NT:**

**GMTs:**

GMT Ratios (post:pre)

<table>
<thead>
<tr>
<th></th>
<th>1 dose</th>
<th>2 doses</th>
<th>(15µg+Alum)</th>
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</thead>
<tbody>
<tr>
<td>4.4</td>
<td>7.3</td>
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</table>

**Per cent responding (4 fold increase):**

≥4 fold in HI after one or two doses:

<table>
<thead>
<tr>
<th></th>
<th>1 dose</th>
<th>2 doses</th>
<th>(15µg+Alum)</th>
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</thead>
<tbody>
<tr>
<td>59%</td>
<td>87%</td>
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</table>

**Per cent responders at specified titer:**

HI ≥40 after one or two doses:

<table>
<thead>
<tr>
<th></th>
<th>1 dose</th>
<th>2 doses</th>
<th>(15µg+Alum)</th>
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<tbody>
<tr>
<td>43%</td>
<td>67%</td>
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</table>

**SRH:**

Per cent with titre (in mm²): None

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: