Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

**Title of Trial:** Safety of adjuvanted and non adjuvanted H1N1 vaccines in children 6 to 35 months of age

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

**Authors/sponsors:** Martine Denis /Sanofi Pasteur

**Study Design:** Phase II randomised trial

**Vaccine:** H1N1 Strain: A/California/07/2009 Manufacturer: Sanofi Pasteur

**Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector):** Inactivated split egg – derived vaccine

**Adjuvant:** AF03 (half or full dose)

**Delivery system:** Intramuscular injection

**Doses (antigen and adjuvant):** 1.9µg, 3.5 µg, 7.5 µg of viral HA protein per dose

**Study population:** 200 children

**Age range:** 6-36 months

**Health status:** Healthy

**Specific inclusion criteria:**

**Specific exclusion criteria**

Clinical Endpoints Assessed

**Safety assessments:** Systemic and local reactions

Immunogenicity assessments:

**Immunoassay type:**

- **HI**

**Neutralization (type of neutralization assay):**

**Others:**

Results:

**Safety:** No safety signals were detected after vaccination, regardless of the vaccine formulation or the dose tested. 21 SAEs reported up to 6 months after vaccination, all assessed as not related

Immunogenicity:

**GMTs**

**GMT Ratios (post:pre)**

Per cent responding (4 fold or greater rise and definition for reporting):

**Per cent responders at specified titer:**

<table>
<thead>
<tr>
<th>HI</th>
<th>eight months after one dose:</th>
</tr>
</thead>
<tbody>
<tr>
<td>6-11m</td>
<td>12-35m</td>
</tr>
<tr>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>1.9µ + half dose AF03</td>
<td></td>
</tr>
<tr>
<td>67%</td>
<td>96%</td>
</tr>
<tr>
<td>7.5 no AF03</td>
<td></td>
</tr>
</tbody>
</table>

Higher levels of antibodies in subjects receiving the adjuvanted vaccine compared to the non adjuvanted vaccine in both age groups

At 8 months after vaccination, most of the subjects vaccinated with the non-adjuvanted vaccine remained seroprotected against the A/H1N1 strain. All subjects vaccinated with the adjuvanted vaccine remained
seroprotected against the A/H1N1 strain. All subjects had detectable HAI Ab

**Status of trial (ongoing/completed):** Completed