Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

Title of Trial: Clinical evaluation of safety and immunogenicity of adjuvanted H1N1 influenza vaccine in adults

Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov): H1N1-007 (GSK registration No)

Authors/sponsors: Dr D.Compens

Study Design: Phase I-II randomized trial. Vaccine was evaluated in comparison with unadjuvanted H1N1 vaccine

Vaccine: H1N1
   Manufacturer: GSK

Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector): Inactivated split vaccine containing the strain A/California/07/2009

Adjuvant: AS03

Delivery system/site: Intramuscular injection

Doses (antigen and adjuvant): 3.75µg per dose - adjuvanted vaccine
   15µg per dose - unadjuvanted vaccine

Study population: 102 children of 18-60 years of age

Age range: Health status: Healthy volunteers

Specific inclusion/exclusion criteria:

Clinical Endpoints Assessed:

Safety assessments:

Immunogenicity assessments:

Results:

Vaccine was assessed as safe and well tolerated

Immunogenicity

<table>
<thead>
<tr>
<th>GMTs</th>
<th>Pre</th>
<th>1 dose</th>
<th>2 doses</th>
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<tbody>
<tr>
<td></td>
<td>9</td>
<td>335</td>
<td>636</td>
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GMT Ratios (post:pre):

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

HI≥4 fold increase after one dose:
   98% (3.75µg+AS03)
   85% (15µg no AS03)

Per cent responders at specified tite:

HI≥40 after one dose:
Others assays:

Status of trial (ongoing/completed): Completed in 2009