Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

Title of Trial: A Two-Part Placebo-Controlled Evaluation of the Safety and Immunogenicity of an A/Indonesia/5/05 Recombinant Hemagglutinin Influenza H5N1 Vaccine with and without Glucopyranosyl Lipid A (GLA-SE) in Healthy Adults 18-49 years of age

Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov): NCT01147068

Authors/sponsors: Dr Manon Cox/Supported by HHS Contract HHS0100200900106C

Study Design: Randomized, prospective, modified double-blinded trial

Vaccine: rH5 Strain: A/Indonesia/5/05

Manufacturer: Protein Science Corporation

Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector): Recombinant HA

Adjuvant: Glucopyranosyl Lipid A (GLA-SE)- Synthetic monophosphoryllipid A-like molecule

In stable emulsion

Delivery system/site: Intramuscular injection

Doses (antigen and adjuvant): Antigen: 3,8 µg, 7.5 µg, 15 µg, 45 µg, 135 µg,

Adjuvant: 1.0 µg GLA

Study population: 394 Adults

Age range: 18-49

Health status: Healthy

Specific inclusion criteria:

Specific exclusion criteria:

Clinical Endpoints Assessed: Frequency of solicited local and systemic reactions (reactogenicity events) in the 7 days post each vaccination. Frequency of adverse events in the 21-day period following each dose. Serious adverse events (SAEs), Adverse Events of Special Interest (AESI), and New Onset of Chronic Illnesses (NOCI) are collected through the end of the study

Safety assessments: Vaccination with PanBlok and PanBlok GLA in SE was generally well tolerated. The frequencies of solicited local injection site pain, local tenderness, muscle pain and fatigue was higher in adjuvanted groups after both doses. The frequency of total unsolicited treatment-related AEs was similar across all groups. Incidences of unsolicited adverse events were similar across study groups (most being mild)

Immunogenicity assessments:

Immunooassay type:

- HAI

Neutralization (type of neutralization assay): NT is pending

Others:

Results:

Safety:

Immunogenicity:

GMTs

GMT Ratios (post:pre)

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

HAI≥4 fold increase after the second vaccination:

39% 135µg no GLA-SE

26% 45µg no GLA-SE

85% 45µg + GLA-SE

68% 15µg + GLA-SE

59% 7.5µg + GLA-SE

66% 3.8µg + GLA-SE

Per cent responders at specified titer:

HAI≥ after the second vaccination:

85% 135µg no GLA-SE

74% 45µg no GLA-SE

100% 45µg + GLA-SE

95% 15µg + GLA-SE
<table>
<thead>
<tr>
<th>Percentage</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>91%</td>
<td>7.5μg + GLA-SE</td>
</tr>
<tr>
<td>91%</td>
<td>3.8μg + GLA-SE</td>
</tr>
</tbody>
</table>

**Others:**

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