Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

Title of Trial: A Two Part Multicenter Study to Investigate the Safety and Immunogenicity of the VAX125 Vaccine in Healthy Adults

Part I: Phase I, Open-Label, Escalating Dose-Ranging Study
Part II: Phase II, Double-Blind Placebo-Controlled Study

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

Authors/sponsors: Alan Shaw, VaxInnate Corp

Study Design (including the phase of clinical trial): Phase 1 Open-Label, Escalating Dose-Ranging Study followed by Phase II, Double-Blind Placebo-Controlled Study

Vaccine subtype: H1

Manufacturer: VaxInnate Corp, USA

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

Adjuvant: Flagellin

Delivery system/site: IM

Doses (antigen and adjuvant, number of doses, intervals between administrations): 0.1-8μg of M2 protein, ... of Flagellin, 1 dose given at day 0

Study population: health adults

Number of subjects involved: 124

Age: 18-49

Health status: Health volunteers

Special inclusion/exclusion criteria:

Clinical Endpoints Assessed

Safety assessments

Part I only: On day of vaccination, study subjects were observed in the clinic for a minimum of 30 minutes post each vaccination and 4 hours (± 60 minutes) post-dose.

Part II only: On day of vaccination, study subjects were observed in the clinic for a minimum of 30 minutes post vaccination. Local and systemic reactogenicity events were captured via clinic visits and telephone contact as applicable using standardized grading. Reactogenicity assessment was also include unsolicited complaints. All local and systemic reactogenicity reporting in the 7 days after immunization were supported with the use of a Memory Aid. This report was reviewed and interpreted by the medical staff. Clinic visit on Days 1, 7 (± 2), 14 (± 2), 28 (± 2) and 180 (± 7) to assess adverse events and clinical labs.

Immunogenicity assessments

Immuoassay type

Serum hemagglutination-inhibition test (HAI) will be assessed at screening and on Day 0 before vaccination, Days 7 (± 2), 14 (± 2), 28 (± 2) and 180 (± 7) after vaccination.

HI Solomon Islands

SRH

Results

Safety:

Reactogenicity: In part 1, 1 of 56 with subjects with fatigue rated as grade 3 (severe) that began several hours after vaccination and lasted for about 4 hours. This subject received the 3 ug dose. In part 2, 1 and 2 ug doses were compared to placebo and all doses were well tolerated.

AEs: none

SAEs: none

Immunogenicity:
Phase 1 results

<table>
<thead>
<tr>
<th>Dose</th>
<th>Control</th>
<th>0.1-0.3</th>
<th>1-3</th>
<th>5-8</th>
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<tbody>
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<td>n=16</td>
<td>n=16</td>
<td>n=56</td>
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<table>
<thead>
<tr>
<th>GMT</th>
<th>Day 0</th>
<th>91</th>
<th>99</th>
<th>102</th>
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<tbody>
<tr>
<td>Day 14</td>
<td>87</td>
<td>190</td>
<td>672</td>
<td>698</td>
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<tr>
<td>Day 28</td>
<td>84</td>
<td>258</td>
<td>640</td>
<td>640</td>
<td></td>
</tr>
</tbody>
</table>

| GMT fold increase | at day 14 | 1.0  | 1.9  | 6.6  | 14.1 |
|                  | at day 28 | 0.9  | 2.6  | 6.2  | 12.9 |

| SR*             | 0      | 5 (31%) | 33 (59%) | 12 (75%) |
| SP**            | 0 of 2 | 4 of 4  | 12 of 13 (92%) | 5 of 6 (83%) |

HI or NT: HAI

SRH: Per cent with titre (in mm²)

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

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

Planned time schedule for next phase of development: Study in elderly planned for fall 2009