Pandemic Influenza Vaccine Clinical Trial Abstract

Minimum information:

Title of Trial: Safety and Immunogenicity of the inactivated whole virus cell-derived H5N1 vaccine in the phase 1 clinical trials, Vabiotech, Vietnam

Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov): No: 1U01CI000347-01

Authors/sponsors: Thu Van Nguyen/ Government of Vietnam and HHS/CDC, US

Study Design (including the phase of clinical trial): The phase I trial.


Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector): Inactivated whole virion adjuvanted vaccine
Adjuvant: AL(OH)3
Delivery system/site: Intramuscularly
Doses (antigen and adjuvant, number of doses, intervals between administrations): 30µg of HA per dose, two doses at day 0 and 28

Study population

Number of subjects involved: 30 Adults Age range: 18-45 years
Health status: Healthy volunteers
Special inclusion criteria:
- Vital signs, especially blood pressure, in the acceptable range
- HBV (-), HIV(-), HCV(-)
- Stable medical conditions

- Exclusion Criteria
  - Immunosuppression
  - Acute or chronic diseases
  - Receipt of Immunoglobulin or any other vaccines during the past 2 weeks
  - Pregnant/baby breast feeding.
  - History of SAEs for any vaccines.

Clinical Endpoints Assessed

Safety assessments:
Immunogenicity assessments: NT and HI at day 0, 28, 42 and 56
Imunoassay type
HI (type of RBC used): Horse Erythrocytes
NT (type of neutralization assay): Micro-Neutralization Test

Results

Safety:
- Reactogenicity: No SAE has been recorded in this study.
  At the first dose, there were 13.33% subjects who had pain at injection site and extended to the day 2nd. Other symptoms were not seen in this study.
  All health indexes as pulse, blood pressure, temperature were within normal limitation after 30 minutes of vaccination.
At the second dose, there were 6.67% subjects who had paint at injection site. Other symptoms were not seen in this study. All health indexes as pulse, blood pressure, temperature were within normal limitation after 30 minutes of vaccination.

**Immunogenicity**

HI or NT: HI

- GMTs: 72.5
- GMT Ratios (post:pre): 9.10
- Per cent responding (4 fold increase): 95.83
- Per cent responders at specified titer: 95.83

SRH: N/A

Per cent with titre (in mm$^2$)

Current status of the clinical trial (completed, ongoing, in preparation): ongoing (phase 2 completed and under analysis)

Date envisaged for availability of results, if not yet available: July 1st, 2009

Planned time schedule for next phase of development:
- Phase 3 (it depends on the decision of MOH): July – September, 2009