Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

Title of Trial: A Phase III, randomised, Controlled, Observed-Blined, Multi-Centre study to Evaluate the Immunogenicity, Safety and Tolerability of Two Doses of Fluad - H5N1 Influenza Vaccine in Adults and Elderly Subjects

Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov): ClinicalTrials.gov, V87P4

Authors/sponsors: A.Banzhoff/Novartis Vaccines

Study Design (including the phase of clinical trial): Phase III, randomized, controlled, observer-blind, multicenter trial


Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector): inactivated subunit egg derived vaccine

Adjuvant: MF59

Delivery system/site: IM injection

Doses (antigen and adjuvant, number of doses, intervals between administrations): 7.5µg with MF59, compared to the licensed MF59-adjuvanted seasonal influenza vaccine Fluad

Study population

Number of subjects involved: appr. 4000 (3000 H5N1, 1000 Fluad)

Age range: >18 years

Health status: healthy subjects

Special inclusion/exclusion criteria: healthy subjects

Clinical Endpoints Assessed

Safety assessments: solicited local and systemic reactions and other adverse events

Immunogenicity assessments

immunoassay type

HI (type of RBC used). Horse red blood cells

NT (type of neutralization assay): microneutralization

SRH yes

Results as presented at ICAAC 2007 in Chicago, IL

Safety:

Reactogenicity: incidence of local and systemic reactions was similar between the vaccine groups with mild pain at the injection site the most common reaction (appr. 50%)

AEs: incidence of AEs was similar between the vaccine groups

SAEs: 8 SAEs at three weeks after the second vaccination, none of them related

Immunogenicity (not presented)

NT:

GMTs

GMT Ratios (post:pre):

Per cent responding (4 fold increase):

Per cent responders at specified titer (titer >/=40):

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

Non-compliance with CCP was observed in several sites and only safety information was reported. The study was replaced by another similar study V87P13, which is still ongoing.

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

Planned time schedule for next phase of development: