Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

Title of Trial: Immunogenicity and Safety of Two Adjuvant Formulations of an Egg-derived Pandemic Vaccine
Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov): ClinicalTrials.gov NCT00562237
Authors/sponsors: Jeroen Medema, Iris de Bruijn / Solvay Pharmaceuticals
Study Design (including the phase of clinical trial): randomized, double blind, placebo-controlled phase I/II safety/efficacy study
Vaccine subtype: H5N1 Strain: A/Vietnam/1194/2004 Manufacturer: Solvay Pharmaceuticals

Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector): inactivated subunit, egg-derived
Adjuvant: AL(OH)3
Delivery system/site: IM injection
Doses (antigen and adjuvant, number of doses, intervals between administrations): 15µg, 30 µg; two doses on days 0 and 21

Study population: healthy adults Number of subjects involved: 407 Age rang: 18-49
Health status: health volunteers
Special inclusion/exclusion criteria

Clinical Endpoints Assessed
Safety assessments
Immunogenicity assessments
  immunoassay type
  HI ( type of RBC used: X
  NT (type of neutralization assay): X
  SRH

Results
Safety:
  Reactogenicity
  AEs
  SAEs

Immunogenicity
  HI or NT:
  GMTs
  GMT Ratios (post:pre)
  Fold increase in HI after 2 doses: 2.6-4.9

Per cent responding (4 fold or greater rise and definition for reporting)
≥4 fold increase of antibody in HI assay:
  After one dose - 20%
  After two doses - 46%
Per cent responders at specified titer

SRH:
Per cent with titre (in mm²)
Current status of the clinical trial (completed, ongoing, in preparation): ongoing

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

Planned time schedule for next phase of development: