Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

Title of Trial: CS03: Randomised, double blind, placebo-controlled, Phase I dose-escalation study of single dose GHB04L1 in healthy adults
Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov): EudraCT 2007-003219-29
Authors/sponsors: V.Vachek/Green Hills Biotechnology,

Vaccine subtype: H5N1    Virus: GNB04L1    Manufacturer: Henogen SA, Belgium
Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector): attenuated intranasal delNS1 vaccine produced in Vero cells. Vaccine approach is based on deletion of NS1 pathogenicity factor inhibiting innate immune response. Due to NS1 deletion vaccine virus can be produced to high titers in Vero cells, but similar to virus like particle vaccine is replication deficient in vivo, so that virus shedding is not observed and the virus is not pathogenic.

Adjuvant: None
Delivery system/site: Intranasal
Doses (antigen and adjuvant, number of doses, intervals between administrations): one application, $10^6.8$, $10^7.2$, $10^7.5$

Study population: Adult    Number of subjects involved: 24    Age range: 18-50
Health status: Healthy voluteers
Special inclusion/exclusion criteria: 

Clinical Endpoints Assessed: End of the study at the end of the August 2009
Safety assessments:
Immunogenicity assessments:
  immunoassay type
  HI (type of RBC used):
  NT (type of neutralization assay):
  SRH

Results
Safety:
  Reactogenicity:
  AEs:
  SAEs:

Immunogenicity

  HI or NT:
  GMTs :
  GMT Ratios (post:pre) :
  Per cent responding (4 fold increase):
  Per cent responders at specified titer:

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

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: